Appendix A. Search Strategies

Database: Ovid MEDLINE(R) without Revisions 1996 to July Week 5 2014, Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations <August 12, 2014>

Population

1 Low Back Pain/
2 Spinal Stenosis/
3 Radiculopathy/
4 Back Injuries/
5 Spinal Injuries/
6 ("low back pain" or (spinal adj3 stenosis) or radiculopathy or radicular).ti,ab.
7 or/1-6

Pharmacologic interventions

8 nsaids.mp. or Anti-Inflammatory Agents, Non-Steroidal/
9 (acetaminophen or paracetamol or aspirin or diflunisal or "choline magnesium trisalicylate" or salsalate or naproxen or ibuprofen or ketoprofen or flurbiprofen or oxaprzin or diclofenac or etodolac or tolmetin of sulindac or meloxicam or piroxicam or meclofenamate or nabumetone or celecoxib).mp.
10 opioids.mp. or Analgesics, Opioid/
11 (alfentanil or alphaprodine or beta-casomorphin$ or buprenorphine or carfentanil or codeine or deltorphin or dextromethorphan or dezocine or dihydrocodeine or dihydromorphine or enkephalin$ or ethylketocyclazocine or ethylmorphine or etorphine or fentanyl or heroin or hydrocodone or hydromorphone or ketobemidone or levorphanol or lofentanil or meperidine or meptazinol or methadone or methadyl acetate or morphine or nalbuphine or opium or oxycodone or oxymorphone or pentazocine or phenazocine or phenoperidine or pirinitramide or promedol or propoxyphene or remifentanil or sufentanil or tilidine or tapentadol or tramadol).mp.
12 antidepressants.mp. or Antidepressive Agents/
13 Antidepressive Agents, Second-Generation/ or Antidepressive Agents, Tricyclic/
14 Serotonin Uptake Inhibitors/
15 (amitriptyline or clomipramine or desipramine or doxepin or imipramine or nortriptyline or citalopram or escitalopram or fluoxetine or paroxetine or sertraline or venlafaxine or duloxetine).mp.
16 skeletal muscle relaxants.mp. or Neuromuscular Agents/
17 (baclofen or carisoprodol or chlorzoxazone or cyclobenzaprine or dantrolene or metaxalone or methocarbamol or orphenadrine or tizanidine).mp.
18 corticosteroids.mp. or Adrenal Cortex Hormones/
19 (prednisone or prednisolone).mp.
20 anticonvulsants.mp. or Anticonvulsants/
21 (gabapentin or pregabalin).mp.

22 Anesthetics, Local/
23 (capsaisin or lidocaine).mp.
24 (22 or 23) and topical.mp.
25 or/8-21
26 24 or 25

Nonpharmacologic interventions
27 Rehabilitation/
28 Physical Therapy Modalities/
29 (rehabilitation adj3 multicomponent).mp.
30 (rehabilitation adj3 interdisciplinary).mp.
31 Cognitive Therapy/
32 exp Psychotherapy/
33 exercise therapy.mp. or Exercise Therapy/
34 exp Complementary Therapies/
35 yoga.mp. or Yoga/
36 tai chi.mp. or Tai Ji/
37 Acupuncture Therapy/ or Acupuncture/ or acupuncture.mp.
38 Massage/ or massage.mp.
39 spinal manipulation.mp. or Manipulation, Spinal/
40 tens.mp. or Transcutaneous Electric Nerve Stimulation/
41 Hot Temperature/tu
42 Cryotherapy/
43 Electric Stimulation Therapy/
44 Traction/ or traction.mp.
45 laser therapy.mp. or Laser Therapy/
46 orthotic devices/ or athletic tape/ or braces/
47 Patient Education as Topic/
48 47 and back pain/
49 "back school$".mp.
50 or/27-46
51 or/48-50
52 7 and (26 or 51)
53 limit 52 to yr="2007 - 2015"

Limit to RCTs
54 randomized controlled trial.mp. or exp Randomized Controlled Trial/
55 randomized controlled trial.pt.
56 controlled clinical trial.mp. or exp Controlled Clinical Trial/
57 controlled clinical trial.pt.

58 clinical trial.mp. or exp Clinical Trial/
59 clinical trial.pt.
60 or/54-59
61 limit 60 to humans

Limit to systematic reviews
62 53 and 61
63 meta-analysis.mp. or exp Meta-Analysis/
64 (cochrane or medline).tw.
65 search$.tw.
66 63 or 64 or 65
67 "Review Literature as Topic"/ or systematic review.mp.
68 66 or 67
69 53 and 68

Limit to controlled observational studies
70 53 and (cohort or control$).mp

Combined searches
71 62 or 69 or 70
72 limit 71 to english language
73 limit 71 to abstracts
74 72 or 73

Database: EBM Reviews - Cochrane Central Register of Controlled Trials <July 2014>

Population
1 Low Back Pain/
2 Spinal Stenosis/
3 Radiculopathy/
4 Back Injuries/
5 Spinal Injuries/
6 ("low back pain" or (spinal adj3 stenosis) or radiculopathy or radicular).ti,ab.
7 or/1-6

Pharmacologic interventions
8 nsaids.mp. or Anti-Inflammatory Agents, Non-Steroidal/
9 (acetaminophen or paracetamol or aspirin or diflunisal or "choline magnesium trisalicylate" or salsalate or naproxen or ibuprofen or ketoprofen or flurbiprofen or oxaprzin or diclofenac or etodolac or tolmetin of sulindac or meloxicam or piroxicam or meclofenamate or nabumetone or

celecoxib).mp.
10 opioids.mp. or Analgesics, Opioid/
11 (alfentanil or alphaprodine or beta-casomorphin$ or buprenorphine or carfentanil or codeine or deltorphin or dextromethorphan or dezocine or dihydrocodeine or dihydromorphine or enkephalin$ or ethylketocyclazocine or ethylmorphine or etorphine or fentanyl or heroin or hydrocodone or hydromorphone or ketobemidone or levorphanol or lofentanil or meperidine or meptazinol or methadone or methadyl acetate or morphine or nalbuphine or opium or oxycodone or oxymorphone or pentazocine or phenazocine or phenoperidine or pirinitramide or promedol or propoxyphene or remifentanil or sufentanil or tilidine or tapentadol or tramadol).mp.
12 antidepressants.mp. or Antidepressive Agents/
13 Antidepressive Agents, Second-Generation/ or Antidepressive Agents, Tricyclic/
14 Serotonin Uptake Inhibitors/
15 (amitriptyline or clomipramine or desipramine or doxepin or imipramine or nortriptyline or citalopram or escitalopram or fluoxetine or paroxetine or sertraline or venlafaxine or duloxetine).mp.
16 skeletal muscle relaxants.mp. or Neuromuscular Agents/
17 (baclofen or carisoprodol or chlorzoxazone or cyclobenzaprine or dantrolene or metaxalone or methocarbamol or orphenadrine or tizanidine).mp.
18 corticosteroids.mp. or Adrenal Cortex Hormones/
19 (prednisone or prednisolone).mp.
20 anticonvulsants.mp. or Anticonvulsants/
21 (gabapentin or pregabalin).mp.
22 Anesthetics, Local/
23 (capsaisin or lidocaine).mp.
24 (22 or 23) and topical.mp.
25 or/8-21
26 24 or 25

Nonpharmacologic interventions
27 Rehabilitation/
28 Physical Therapy Modalities/
29 (rehabilitation adj3 multicomponent).mp.
30 (rehabilitation adj3 interdisciplinary).mp.
31 Cognitive Therapy/
32 exp Psychotherapy/
33 exercise therapy.mp. or Exercise Therapy/
34 exp Complementary Therapies/
35 yoga.mp. or Yoga/
36 tai chi.mp. or Tai Ji/
37 Acupuncture Therapy/ or Acupuncture/ or acupuncture.mp.

38 Massage/ or massage.mp.
39 spinal manipulation.mp. or Manipulation, Spinal/
40 tens.mp. or Transcutaneous Electric Nerve Stimulation/
41 Hot Temperature/tu
42 Cryotherapy/
43 Electric Stimulation Therapy/
44 Traction/ or traction.mp.
45 laser therapy.mp. or Laser Therapy/
46 orthotic devices/ or athletic tape/ or braces/
47 Patient Education as Topic/
48 47 and back pain/
49 "back school$".mp.

Combined searches
50 or/27-46
51 or/48-50
52 7 and (26 or 51)
53 limit 52 to yr="2007 - 2015"

Database: EBM Reviews - Cochrane Database of Systematic Reviews <2005 to June 2014>

1 "low back pain".ti.
2 limit 1 to full systematic reviews

Appendix B. Inclusion and Exclusion Criteria

	Include	Exclude
Population	Adults with acute, subacute, or chronic nonradicular low back pain, radicular low back pain, or symptomatic spinal stenosis.	Children, pregnant women Patients with low back pain related to cancer, infection, inflammatory arthropathy, high velocity trauma, fracture; or low back pain associated with severe or progressive neurological deficits
Interventions	KQ 1: Nonsteroidal anti-inflammatory drugs (NSAIDs) Nonopioid analgesics, such as acetaminophen Opioid analgesics, such as oxycodone, hydrocodone, hydromorphone, morphine, fentanyl Antidepressants, such as tricyclic antidepressants, serotonin-norepinephrine reuptake inhibitors (SNRIs), and selective serotonin-reuptake inhibitors (SSRIs), or serotonin antagonist and reuptake inhibitors (SARIs) Skeletal muscle relaxants, including benzodiazepines Corticosteroids, such as prednisone or prednisolone Anti-epileptic drugs, such as gabapentin or pregabalin Capsaicin or topical lidocaine	Parenterally administered medications
	KQ 2: Interdisciplinary or multicomponent rehabilitation Psychological therapies, such as cognitive behavioral therapy Exercise and related interventions, such as yoga or Tai Chi Complementary and alternative medicine therapies: spinal manipulation, acupuncture, massage Passive physical modalities: heat, cold, ultrasound, transcutaneous electrical nerve stimulation (TENS), electrical muscle stimulation (EMS), interferential therapy (IFT), traction, low level laser therapy, lumbar supports/braces Back schools Other noninvasive treatments, such as taping	Invasive, nonsurgical therapies (e.g., injections) and surgical therapies
Comparators	Any included intervention(s) versus any other included intervention(s); noninvasive, nonsurgical treatment options, alone or in combination (which may include both nonpharmacological and pharmacological) components. Other possible comparators include placebo (drug trials), sham (functionally-inert) treatments, or no treatment.	
Outcomes	Benefits (effectiveness): Reduction or elimination of low back pain, including related leg symptoms Improvement in back-specific and overall function Improvement in health-related quality of life (HRQOL) Reduction in work disability/return to work Global improvement Number of back pain episodes or time between episodes Patient satisfaction	
	Harms: Pharmaceutical: serious (anaphylaxis, death) and nonserious (mild allergic or untoward) drug reactions or effects; opioid addiction or overdose Nonpharmaceutical: serious (death, neurological including cauda equine syndrome, fracture, local skin burns, etc.) and nonserious (mild transient local or general soreness, stiffness, aching; local skin irritation, etc.)	
Timing	Duration of followup: short term (up to 6 months) and long term (at least 1 year)	
Setting	Any nonhospital setting or in self-directed care	

Appendix C. Included Studies

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Appendix D1. Studies in an Included Systematic Review, not Directly Used in Current Review

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Appendix D2. Excluded Studies

Chiropractic and yoga as an effective combination therapy for the treatment of low back pain: A randomised controlled trial. Clinical Chiropractic. 2012;15(2):85. PMID: No PMID. Excluded: not a study.

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Appendix E1. Trials of Acetaminophen Included in the APS/ACP Review

Author, Year, Title	Purpose of Study	Study Design	Inclusion Criteria	Exclusion Criteria	Number of Treatment and Control Subjects (number approached, number eligible, number enrolled)
Doran, 1975 Manipulation in low back pain: a multicenter study	Not stated in paper. To compare manipulation vs. definitive physiotherapy, corset, or analgesics in treatment of low back pain.	Multicenter randomized trial	Age 20-50 Painful limitation of movement in lumbar spine Suitable for any of the 4 treatments	Psychological disturbance, pregnancy, deviation of lumbar spine from vertical of over 15 degrees, significant root pain in 1 or both legs, straight leg raising reduced to < 30 degrees on either side, continuous paraesthesia or that linked to weight bearing, associated disturbances of micturition, abnormal reflexes, sensory loss, significant weakness, or wasting due to latest attack. osteoarthritis of hip, sacroiliitis, significant radiological osteoporosis, previous manipulation, corset wearing, other	Number approached and eligible not reported. 456 total. 116 manipulation, 114 physiotherapy, 109 corset, 113 analgesics
Evans, 1980 Medicine of choice in low back pain **(also in Aspirin)**	To compare the efficacy of aspirin, dextropropoxyphene plus paracetamol, indomethacin, mefenamic acid, paracetamol, and phenylbutazone for low back pain	RCT with multiple crossovers	Primary complaint of low back pain, moderate intensity, from mechanical or degenerative condition. Pain between the level of the inferior angles of the scapulae and the lower sacrum. Sciatic or femoral root pain ok. Ambulatory and outpatient.	Pregnant, concomitant disease	Number approached and eligible not reported 60 enrolled

Appendix E1. Trials of Acetaminophen Included in the APS/ACP Review

Author, Year, Title	Subject Age, Gender, Diagnosis	Country and Setting	Sponsor	Measures
Doran, 1975 Manipulation in low back pain: a multicenter study	Mean age: not reported. About equal numbers in the 3rd, 4th and 5th decades of life Female gender: 211/456 (46%) Diagnosis: painful limitation of movement in the lumbar spine	7 hospitals in England	None reported	History of LBP, characteristics of present attack, results of clinical examination (presence of lumbar lordosis, deviation from midline, limitation of 4 lumbar movements by pain, distance from fingertip to floor at maximal comfortable flexion, straight leg raise, femoral nerve stretch test, decrease in muscle power, knee and ankle reflexes, and presence of impaired sensation. Clinical severity rated as mild, moderate or severe.
Evans, 1980 Medicine of choice in low back pain **(also in Aspirin)**	Mean age: 47 years Female gender: 67% Race: not reported Duration of pain and baseline pain intensity not reported	U.K. Single center Clinic setting not clear	Parke-Davis, Welsh National School of Medicine	Spinal anterior flexion Pain: 4 point categorical scale (0=nil to 3-severe) Overall assessment: 'best' and 'worst' medications

Appendix E1. Trials of Acetaminophen Included in the APS/ACP Review

Author, Year, Title	Type of Intervention	Results
Doran, 1975 Manipulation in low back pain: a multicenter study	Randomized to referral to one of 4 treatments: Manipulation: provider chose technique. May have included mobilizing and soft tissue techniques. ≥ 2 treatments/week, average 6.0 treatments. Definitive physiotherapy: any treatment within usual practice of department except physiotherapy. ≥ 2 treatments/week, average 7.3. Corset: hospital decided in advance which type of corset it would use during trial. Corset applied day of trial entry. No information on duration of wear. Analgesics: 2 paracetamol tablets every 4 hours. Paracetamol also "given to patients in the other 3 treatment groups to be taken as required" All patients given postural advice and chart.	Immediately post-treatment: no difference between treatments for pain, other clinical values or patient or doctor assessment of condition. 3 weeks post-treatment: 153/340 (45%) patients had additional treatment since end of treatment phase. No differences in pain among treatments except left-side bending was limited by pain in 25% of analgesic and 14% of other groups. No difference in patient or doctor condition assessment. 3 month followup: No difference in pain among treatments 12 month followup: No difference in pain among treatments
Evans, 1980 Medicine of choice in low back pain **(also in Aspirin)**	A: Dextropropoxyphene/paracetamol 260 mg/2600 mg per day B: Aspirin 3600 mg/day C: Indomethacin 150 mg/day D: Mefenamic acid 1500 mg/day E: Paracetamol 4000 mg/day F: Phenylbutazone 300 mg/day Patients randomized to 3 drugs, each administered consecutively for 1 week each	Dextropropoxyphene/paracetamol (A) vs. aspirin (B) vs. indomethacin (C) vs. mefenamic acid (D) vs. paracetamol (E) vs. phenylbutazone (F) Mean daily pain index (0 to 3 scale, 3=severe): 1.713 vs. 1.425 vs. 1.487 vs. 1.375 vs. 1.660 vs. 1.433 ($p<0.05$ for D vs. A or E; $p<0.05$ for B vs. A) Patient preferences (1=best, 2-middle, 3=worst): 2.07 vs. 2.37 vs. 1.98 vs. 1.75 vs. 2.15 vs. 1.68 ($p<0.005$ for B vs. D or F)

Appendix E1. Trials of Acetaminophen Included in the APS/ACP Review

Author, Year, Title	Duration of Followup	Loss to Followup	Compliance to Treatment	Adverse Events and Withdrawals Due To Adverse Events	Quality Rating	Comments
Doran, 1975 Manipulation in low back pain: a multicenter study	3 weeks treatment, with followup exams at 3 weeks post-treatment. Questionnaires at 3 months and 12 months after 1st assessment.	68/456 (15%) did not complete 3 week treatment 116/456 (25%) did not complete 1st followup 121/456 (27%) did not complete 2nd followup 194/456 (43%) did not complete 3rd followup	Not reported	Not reported		Interventions not standardized or well-controlled. Many received treatment after treatment period, some of which was a combination of all interventions (% who received combination treatment not provided).
Evans, 1980 Medicine of choice in low back pain **(also in Aspirin)**	3 weeks (1 week for each of three random interventions)	2/60 (3.3%)	Percentage of recommended dose of trial medication taken: 72% vs. 80% vs. 76% vs. 92% vs. 90% vs. 96% Defaults (patient took fewer than prescribed number of tablets on any of the 6 non-clinic days for which that treatment was prescribed): 17/30 (57%) vs. 13/30 (43%) vs. 14/30 (47%) vs. 8/30 (27%) vs. 9/30 (30%) vs. 6/30 (20%)	Dextropropoxyphene/paracetamol (A) vs. aspirin (B) vs. indomethacin (C) vs. mefenamic acid (D) vs. paracetamol (E) vs. phenylbutazone (F) Withdrawal due to adverse events: Not reported Any side effects: 19/30 (63%) vs. 20/30 (67%) vs. 19/30 (63%) vs. 12/30 (40%) vs. 13/30 (43%) vs. 14/30 (47%) Neurological side effects: 15/30 vs. 11/30 vs. 16/30 vs. 8/30 vs. 8/30 vs. 8/30 GI side effects: 9/30 vs. 12/30 vs. 8/30 vs. 6/30 vs. 8/30 vs. 6/30		

Appendix E1. Trials of Acetaminophen Included in the APS/ACP Review

Author, Year, Title	Purpose of Study	Study Design	Inclusion Criteria	Exclusion Criteria	Number of Treatment and Control Subjects (number approached, number eligible, number enrolled)
Hackett, 1988 Electroacupuncture compared with paracetamol for acute low back pain	To compare the effectiveness of electroacupuncture with paracetamol for the treatment of low back pain	RCT	Age 16 - 60 Low back pain < 3 days duration	Not reported	40 consecutive patients were approached and enrolled. Random allocation to Group A (electroacupuncture + dummy paracetamol tablets) or B (paracetamol + dummy electroacupuncture). Number of patients in each group not reported
Hickey, 1982 Chronic low back pain: a comparison of diflunisal with paracetamol	To compare clinical response and safety of diflunisal (100 mg/d) with paracetamol (4000 mg/d).	RCT	Chronic LBP, severely troubled by symptoms from 6 months to many years and unresponsive to previous treatments.	Pain from intervertebral disc prolapse, suspected neoplastic disease, neurological disease, pregnancy, peptic ulcer or gastric hemorrhage, current systemic corticosteroids or anticoagulants, liver or kidney disease, hemopoietic disorders, psychiatric problems, history of sensitivity to salicylates or paracetamol.	Number approached and eligible not reported. 30 consented and enrolled: 16 diflunisal and 14 paracetamol

Appendix E1. Trials of Acetaminophen Included in the APS/ACP Review

Author, Year, Title	Subject Age, Gender, Diagnosis	Country and Setting	Sponsor	Measures
Hackett, 1988 Electroacupuncture compared with paracetamol for acute low back pain	Mean age: not reported. Range 16-60 Female gender: not reported Race: not reported Baseline pain: Group A 54.5 VAS, Group B 52.7 VAS Duration of pain: < 3 days Diagnosis: LBP < 3 days duration	England 5-partner rural training practice of 10,000 patients	Not reported	At baseline, full clinical history, straight-leg raising assessed with resulting pain and its location. Muscle power, reflexes and sensory impairment recorded. Patient and doctor completed VAS for pain and mobility. At 1 week, 2 and 6 weeks post-treatment, VAS, time away from work, self-medication, and any side effects attributed to treatment recorded. Telephone followup at 6 and 12 months, along with review of medical records for recurrence and additional medical intervention.
Hickey, 1982 Chronic low back pain: a comparison of diflunisal with paracetamol	Mean age: diflunisal - 40.4 paracetamol - 45.7 Female gender: 87% Race: not reported Baseline pain: not reported Duration of pain: $\geq$ 6 months Diagnosis: chronic low back pain	New Zealand outpatient pain clinic	Merck, Sharp and Dohme supplied the drugs	Evaluations at initial visit (week -1), 2nd visit (week 0), end of 2 weeks of treatment (week 2), and after 4 weeks of treatment (week 4). Subjective and objective evaluations of clinical and physical signs: low back pain, irradiating pain, functional disability, limitation or pain on spinal extension (all of the proceeding measured by 0-3 scale), forward bending (1-3 scale), patient overall rating of treatment efficacy (0-3 scale). Hemoglobin estimate, hematocrit, platelet estimate, white blood cell count, differential counts, blood urea, creatinine, SGOT, and alkaline phosphates measured at weeks -1, 2 and 4, with variations form norm noted. All AEs reported or observed were assessed.

Appendix E1. Trials of Acetaminophen Included in the APS/ACP Review

Author, Year, Title	Type of Intervention	Results
Hackett, 1988 Electroacupuncture compared with paracetamol for acute low back pain	Group A: electroacupuncture + dummy paracetamol tablets. 2 treatments provided within 24 hours of study entry using Asah Unit (low amplitude, pulsed square wave) and placebo paracetamol, with instructions to take 2 tablets every 4 hours as needed for pain Group B: paracetamol + dummy electroacupuncture. Same electroacupuncture procedure as above except with no electrical current passed on to patient's skin. 2 paracetamol tablets (mg measurement not provided) every 4 hours for pain as needed. Each patient given card with advice on posture, sleeping position and lifting methods. Not clear if only Group B given this card.	Group A (electroacupuncture + dummy paracetamol) vs. Group B (paracetamol + dummy electroacupuncture) Within group differences reported Pain VAS: Initial, Week 1, Week 2, Week 6 54.5, 23.4, 22.0, 13.7 vs. 52.7, 23.2, 18.3, 3.3 p>0.01 for Week 6, NS at other time points Mobility VAS: Initial, Week 1, Week 2, Week 6 51.2, 25.2, 17.0 vs. 53.4, 26.5, 17.8 p>0.01 for Week 6, NS at other time points
Hickey, 1982 Chronic low back pain: a comparison of diflunisal with paracetamol	48 hour wash-out A. Diflunisal 500 mg 2x/day B. Paracetamol 1000 mg 4x/day	Group A (diflunisal) vs Group B (paracetamol) Week 2 LBP: none 3 patients vs 2 patients, mild 8 vs 7, moderate 3 vs 3, severe 2 vs 0 Irradiating pain: none 7 vs 6, mild 4 vs 3, moderate 4 vs 2, severe 1 vs 1 Functional disability: none 2 vs 2, mild 8 vs 7, moderate 4 vs 4, severe 2 vs 0 Limitation of pain on spinal extension: none 6 vs 2, mild 2 vs 6, moderate 8 vs 4, severe 0 vs 0 Forward bending: can reach knees 0 vs 0, mid calf 6 vs 2, ankle 10 vs 10 Week 4 LBP: none 5 vs 3, mild 8 vs 4, moderate 2 vs 5, severe 1 vs 0 Irradiating pain: none 10 vs 8, mild 4 vs 1, moderate 1 vs 2, severe 1 vs 1 Functional disability: none 6 vs 2, mild 7 vs 7, moderate 1 vs 2, severe 2 vs 1

Appendix E1. Trials of Acetaminophen Included in the APS/ACP Review

Author, Year, Title	Duration of Followup	Loss to Followup	Compliance to Treatment	Adverse Events and Withdrawals Due To Adverse Events	Quality Rating	Comments
Hackett, 1988 Electroacupuncture compared with paracetamol for acute low back pain	VAS at 1 week, 2 and 6 weeks. Telephone followup and scrutiny of medical records at 6 and 12 months	37/41 (90%) completed	Monitored by tablet counting but explicit data on compliance to study meds not reported. Discussion section noted Group A: 1 patient took NSAID Group B: 2 patients took NSAIDs and 1 consulted with osteopath.	No treatment-related AEs. Group A: 1 patient complained of severe pain before treatment initiation and was given an NSAID. Group B: 2 patients complained of severe pain within 24 hours of trial start and required treatment with NSAIDs.		Results data confusing. Table 1 labels not congruent with text description of Groups A and B. P of >0.01 is described as significant
Hickey, 1982 Chronic low back pain: a comparison of diflunisal with paracetamol	4 weeks of treatment	1/30 (3%) did not complete	A. No report of compliance data - full compliance implied B. 1 took extra analgesics. 1 failed to complete treatment due to depression	A. 1 patient mild nausea, 1 mild generalized bleeding and bleeding from the nose B. 1 patient reported depression and headaches "but was found to be a chronic depressive" No patients had adverse lab values		Very small n

Appendix E1. Trials of Acetaminophen Included in the APS/ACP Review

Author, Year, Title	Purpose of Study	Study Design	Inclusion Criteria	Exclusion Criteria	Number of Treatment and Control Subjects (number approached, number eligible, number enrolled)
Moore, 1999 The PAIN study: paracetamol, aspirin and ibuprofen new tolerability study **Abstracted in aspirin**	To directly compare aspirin, ibuprofen, and paracetamol for safety in general practice setting for short-term analgesia.	Randomized, multi-center, blinded, parallel group trial			8677 adults 2900 - aspirin 2886 - ibuprofen 2888 - paracetamol
Peloso, 2004 Analgesic efficacy and safety of tramadol/ acetaminophen combination tablets (Ultracet) in treatment of chronic low back pain: a multicenter, outpatient, randomized, double-blind, placebo controlled trial **Abstracted in tramadol**	To evaluate the analgesic efficacy and safety of tramadol /acetaminophen combination tablets for treatment of chronic low back pain (LBP).	RCT	Chronic LBP requiring daily medications for at least 3 months, >18 year, good general health; females postmenopausal, incapable of becoming pregnant, or using appropriate contraception with a negative pregnancy test within 1 week of study entry	Recent use of sedative hypnotics, short-acting analgesics, topical medications or preparations, or muscle relaxants; recent use of medications that could reduce the seizure threshold; recent use of opioids or initiation of nutraceuticals; significant comorbid conditions; substance abuse; neurological deficits in lower extremities; most patients with prior back surgery, unstable spine, symptomatic disc herniation, severe spinal stenosis, tumor of back, spondylolisthesis >= Grade 2	Number approached and eligible not reported 338 enrolled 336 (99.4%) analyzed; 167 drug, 169 placebo

Appendix E1. Trials of Acetaminophen Included in the APS/ACP Review

Author, Year, Title	Subject Age, Gender, Diagnosis	Country and Setting	Sponsor	Measures
Moore, 1999 The PAIN study: paracetamol, aspirin and ibuprofen new tolerability study **Abstracted in aspirin**	Adults 18-75, all requiring short-term analgesic treatment of mild to moderate pain. aspirin: mean age 43.6 yrs, 57.9% female ibuprofen: mean age 43.3 yrs, 58.3% female paracetamol: mean age 43.6 yrs, 57.9% female 48% of trial population/NSAID indication for musculoskeletal or back pain of which, 15.87% for "backache"	France - 1108 General Practitioners	Boots Healthcare Intl.	Patients used a diary to record adverse events & severity (serious, severe, or mild), medication taken, and global opinion of treatment at end of diary according to a 4-pt scale. Specific instructions on reporting events was provided to patients in diary. Diary & unused medications returned after treatment period (1-7 days) GP called patient day after expected treatment to start to ensure treatment started & record or qualify early AE. Classification & coding of events identified & graded from patient diary, phone calls, and further GP visits. Classification & coding (COSTART) of events checked by a Study Safety Committee before unblinding.
Peloso, 2004 Analgesic efficacy and safety of tramadol/ acetaminophen combination tablets (Ultracet) in treatment of chronic low back pain: a multicenter, outpatient, randomized, double-blind, placebo controlled trial **Abstracted in tramadol**	Mean age 57.5 years 62.5% female Non-white race: 6% Baseline pain VAS (0-100): 68	Canada 30 outpatient centers, including university clinics and private practices	Ortho-McNeil Pharmaceutical	Patients evaluated on days 1, 14, 28, 56 and 91. VAS: back pain experienced in previous 48 hours Pain Relief Rating Scale (starting at day 14) Short-Form McGill Pain Questionnaire (SF-MPQ) (days 1 and 91) measuring 15 pain descriptors with sensory and affective components. Roland Disability Questionnaire (RDQ) (days 1 and 91) evaluating features of health status most affected by LBP. Medical Outcome Study Short Form-36 (SF-36) Health Survey Patient-investigator overall medication assessments

Appendix E1. Trials of Acetaminophen Included in the APS/ACP Review

Author, Year, Title	Type of Intervention	Results
Moore, 1999 The PAIN study: paracetamol, aspirin and ibuprofen new tolerability study **Abstracted in aspirin**	Treatment (all groups, 3 medications): at least 1 and at most 7 days for mild to moderate pain, started within 24 hours of consultation w/ GP. aspirin: 500mg tabs - up to 3 g daily ibuprofen: 200 mg tabs - up to 2 g daily paracetamol: 500mg tabs - up to 3 g daily	7-9 days after start of treatment (1 to 7 day treatment duration)
Peloso, 2004 Analgesic efficacy and safety of tramadol/ acetaminophen combination tablets (Ultracet) in treatment of chronic low back pain: a multicenter, outpatient, randomized, double-blind, placebo controlled trial **Abstracted in tramadol**	A: Tramadol 37.5 mg/acetaminophen 325 mg (tramadol/APAP) combination tablets titrated to average dose 4.2 tablets drug (tramadol 158 mg/APAP 1369 mg) day B: Placebo	Tramadol/APAP vs. placebo Final pain score (VAS 0-100), means: 47.4 vs. 62.9; p< 0.001 Pain relief scores (6 point Likert scale, 1=slight relief and 2=moderate relief): 1.8 vs. 0.7; p< 0.001 Final pain relief rated "complete" or "a lot": 40% (65/163) vs. 13% (22/165) Withdrew due to insufficient pain relief: 30/167 (18%) vs. 48% (82/169) Overall assessment very good or good: 64% vs. 25% (p<0.001) SF-36-MPQ, Total score (mean change): -6.1 vs. -2.5, p=0.011 SF-36-MPQ, Present pain index: -1.0 vs. -0.4, p<0.001 RDQ, Total score (mean change): -2.4 vs. -1.3, p=0.043 RDQ, Bothersomeness (mean change): -1.5 vs. -0.3, p<0.001 SF-36, Physical functioning (mean change): 7.7 vs. 2.3, p=0.017 SF-36, Body pain (mean change): 11.2 vs. 1.6, p<0.001 SF-36, Physical component summary (mean change): 3.5 vs. 1.5, p=0.018 SF-36, Mental component summary (mean change): 0.8 vs. -0.5, p=0.372

Appendix E1. Trials of Acetaminophen Included in the APS/ACP Review

Author, Year, Title	Duration of Followup	Loss to Followup	Compliance to Treatment	Adverse Events and Withdrawals Due To Adverse Events	Quality Rating	Comments
Moore, 1999 The PAIN study: paracetamol, aspirin and ibuprofen new tolerability study **Abstracted in aspirin**	8233/8677 (94.9%) completed (5 lost to followup, 55 withdrew for other reasons) 2890/2900 (99.7%) on aspirin	8233 adhered to study protocol - no analysis	Rates of significant AEs: aspirin: 18.7%; ibuprofen: 13.7%; paracetamol: 14.5%. ibuprofen & paracetamol were significantly better tolerated than aspirin (p< 0.001). Total GI events (incl. Dyspepsia) & abdominal pain were less frequent with ibuprofen (4 & 2.8% respectively) than with paracetamol (5.3 & 3.9%) or aspirin (7.1 & 6.8%) [all p< 0.035]. 6 cases of non-serious GI bleeding, 4 with paracetamol and 2 with aspirin; one case of peptic ulcer with aspirin.		NEED TO ADD	JGS Abstracted, missing some points - needs review by LH or RC
Peloso, 2004 Analgesic efficacy and safety of tramadol/ acetaminophen combination tablets (Ultracet) in treatment of chronic low back pain: a multicenter, outpatient, randomized, double-blind, placebo controlled trial **Abstracted in tramadol**	Final measurement at end of 3 month treatment period.	2 placebo patients excluded due to lack of post-baseline data. Of 338 randomized, 147 (43.5%) completed the 91 day double-blind phase; 86 (51.5%) in the drug and 61 (35.7%) in the placebo group.	Not reported.	Tramadol + acetaminophen vs. placebo Withdrawals due to adverse events: 47/167 (28.1%) vs. 13/169 (7.6%) Deaths: None Nausea: 42/167 (25%) vs. 10/169 (5.9%) Dizziness: 30/167 (18%) vs. 12/169 (7.1%) Constipation: 37/167 (22%) vs. 13/169 (7.7%) Somnolence: 28/167 (17%) vs. 5/169 (3.0%) Headache: 47/167 (28%) vs. 37/169 (22%)		Decrease of 30% in pain intensity considered to be clinically meaningful. This trial replicates Mullican 2001.

Appendix E1. Trials of Acetaminophen Included in the APS/ACP Review

Author, Year, Title	Purpose of Study	Study Design	Inclusion Criteria	Exclusion Criteria	Number of Treatment and Control Subjects (number approached, number eligible, number enrolled)
Ruoff, 2003 Tramadol/ acetaminophen combination tablets for the treatment of chronic lower back pain: a multicenter, randomized, double-blind, placebo-controlled outpatient study **Abstracted in tramadol**	To assess the 3 month efficacy and safety of tramadol/acetaminophen combination tablets in treatment of chronic lower back pain.	Randomized, multicenter, double-blind, placebo-controlled study	Age 25-75, in general good health, in general good health, ambulatory, low back pain requiring daily medication for >=3 months prior to entry; females postmenopausal, surgically sterile, or practicing an acceptable method of contraception; pain score >=40 mm on 0-100 scale after screening/washout phase	Previously discontinued tramadol due to adverse events, tramadol within 30 days of study entry; recent antidepressants, cyclobenzaprine, antiepileptic drugs for pain, TENS, manipulation, acupuncture; recent sedative-hypnotics, short-acting analgesics, topical anesthetics, or muscle relaxants; steroid injection within 3 months; severe pain elsewhere than lower back or lower extremity neurological deficits; substance abuse, major psychiatric disorders, pregnant or lactating	Number approached and eligible not reported 322 randomized 318 (161 drug and 157 placebo) analyzed
Stein, 1996 The efficacy of amitriptyline and acetaminophen in the management of acute low back pain	1) To compare efficacy of amitriptyline vs. acetaminophen in acute LBP 2) To evaluate whether the efficacy of amitriptyline in acute LBP is associated with its antidepressant properties Only 1) is abstracted here	RCT	1st episode of pain in lumbosacral region, with or without sciatic radiation, lasting up to 6 months	Over age 60, other physical disorders or psychiatric disturbance	65 screened, 50 met criteria, 45 enrolled, 39 participated: 20 amitriptyline, 19 control. 14/39 (36%) women.

Appendix E1. Trials of Acetaminophen Included in the APS/ACP Review

Author, Year, Title	Subject Age, Gender, Diagnosis	Country and Setting	Sponsor	Measures
Ruoff, 2003 Tramadol/ acetaminophen combination tablets for the treatment of chronic lower back pain: a multicenter, randomized, double-blind, placebo-controlled outpatient study **Abstracted in tramadol**	Mean age 53.9 years 63.2% female Non-white race: 8% vs. 12% Baseline pain score 70.0mm (0-100 mm VAS)	USA (implied) 29 sites	Protocol CAPSS-112 Study Group 4/5 authors noted affiliation with Ortho-McNeil Pharmaceutical, Inc.	PVA scores: patient assessment of back pain during previous 48 hours on scale of 0mm to 100mm. Rated on study visit days 1, 14, 28, 56, and 91. Pain Relief Rating Scale (PRRS) scores Short-Form McGill Pain Questionnaire (SF-MPQ): patients rated 15 pain descriptors (including sensory and affective components) for severity and present pain intensity. Day 1 of double-blind and final visit. Roland Disability Questionnaire (RDQ): assesses components of health status believed to be most affected by lower back pain, including physical function, feelings of well-being, bothersomeness and difficulty performing activities of daily living. Day 1 of double-blind and final visit. 36-Item Short-Form Health Survey (SF-36) scores: assesses physical, social and mental well-being. Day 1 of double-blind and final visit. Overall assessment of medication by patients and doctors Incidence of discontinuation due to insufficient pain relief (Kaplan-Meier analysis) Data on vital signs, physical examination, serum chemistry, hematology, urinalysis and adverse events were collected throughout double-blind at protocol-specified visits.
Stein, 1996 The efficacy of amitriptyline and acetaminophen in the management of acute low back pain	Mean age: 36 Female gender: 14/39 (36%) Race: Baseline pain: Duration of pain: Diagnosis: acute LBP, with or without sciatic radiation, $\geq$ 6 months duration.	Israel emergency service in hospital	None reported	Before study: medical, neurological and orthopedic evaluations. Baseline labs: blood count, blood sugar, urea, electrolytes, liver functions, urinalysis, electrocardiogram, x-ray of lumbosacral region. Beck Depression Inventory (BDI): self-rating scale to evaluate level of depression Spielberger State-Trait Anxiety Inventory (STAI): self-rating scale evaluating level of anxiety Shanan Sentence Completion Test (SSCT): self-administered semi projective test evaluating coping along various dimensions UCLA pain profile (UCLA-PP): evaluates pain intensity and pain-affective dimension - maximal, minimal & usual pain experience. BDI, STAI and SSCT given at beginning and end of study. UCLA-PP and orthopedic evaluations repeated each week.

Appendix E1. Trials of Acetaminophen Included in the APS/ACP Review

Author, Year, Title	Type of Intervention	Results
Ruoff, 2003 Tramadol/ acetaminophen combination tablets for the treatment of chronic lower back pain: a multicenter, randomized, double-blind, placebo-controlled outpatient study **Abstracted in tramadol**	3 week screening/washout, then those with PVA scores ≥ 40 mm randomly assigned to: A: Tramadol 37.5 mg/APAP 325 mg oral tablets (titrated to mean of 4.2 tablets/day) B: Placebo	Tramadol/acetaminophen vs. placebo Final pain score (0-100 mm scale), means: 44.4 vs 52.3 (p=0.015) >30% reduction in pain score: 55% vs. 40% (p=0.011) >50% reduction in pain score: 44% vs. 32% (p=0.044) Pain relief score (-1 to 4 scale), means: 1.8 vs. 1.1 (p<0.001) SF-MPQ, sensory component, mean changes: -6.5 vs. -3.5, p=0.011 SF-MPQ, affective component, mean changes: -1.9 vs. -1.3, p=0.235 SF-MPQ, present pain index, mean changes: -1.1 vs. -0.8, p=0.011 SF-MPQ, total score, mean changes: -8.4 vs. -4.8, p=0.021 RDQ, bothersomeness, mean changes: -2.2 vs. -1.4, p=0.027 RDQ, total score, mean changes: -4.1 vs. -2.6, p=0.023 SF-36, Physical functioning, mean change: 10.9 vs. 7.5, p=0.328 SF-36, Role-physical, mean change: 29.0 vs. 14.0, p=0.005 SF-36, Bodily pain, mean change: 16.1 vs. 10.7, p=0.046 SF-36. Physical component summary, mean change: 6.1 vs. 4.2, p=0.161 SF-36, Mental component summary, mean change: 3.9 vs. 1.2, p=0.008
Stein, 1996 The efficacy of amitriptyline and acetaminophen in the management of acute low back pain	1 week wash-out. Group A: amitriptyline or Group B:acetaminophen in fixed-dose, controlled double-blind design. Identical capsules, 4x/day for 5 consecutive weeks. Dose gradually increased over 4 days to therapeutic level. Amitriptyline: 150 mg/day Acetaminophen: 2000 mg/day	Group A more effective vs. Group B in reducing pain intensity from the 2nd week of treatment (week 3, p=0.060; week 4, p=0.072; week 5, p=0.045; week 6, p=0.096). Repeated measures analysis of variance showed significant effects of amitriptyline, gender (women rating higher), and time. Both groups had improvement in pain at end of treatment; Group A 79% vs. 75% Group B reported reduction in pain intensity.

Appendix E1. Trials of Acetaminophen Included in the APS/ACP Review

Author, Year, Title	Duration of Followup	Loss to Followup	Compliance to Treatment	Adverse Events and Withdrawals Due To Adverse Events	Quality Rating	Comments
Ruoff, 2003 Tramadol/ acetaminophen combination tablets for the treatment of chronic lower back pain: a multicenter, randomized, double-blind, placebo-controlled outpatient study **Abstracted in tramadol**	Total study time was 91 days	31 in drug and 59 in placebo group withdrew due to insufficient pain relief.	Not reported.	Tramadol + acetaminophen vs. placebo Any adverse events: 111/161 (68.9%) vs. 73/157 (46.5%) AE's judged related to medication: 38/161 (23.6%) vs. 6/157 (3.8%) Withdrawal due to adverse events: 30/161 (18.6%) vs. 9/157 (5.7%) Nausea: 13.0% vs. 3.2%, p=0.001 Somnolence: 12.4% vs. 1.3%, p<0.001 Constipation: 11.2% vs. 5.1%, p=0.03 Headache: 8.7% vs. 3.8%, p=0.08 Dizziness: 7.5% vs. 1.9%, p=0.02 pruritus (6.8% vs 1.3%, p=0.02) No serious AEs related to study medication reported.		
Stein, 1996 The efficacy of amitriptyline and acetaminophen in the management of acute low back pain	5 week treatment duration only	5.1% drop-out due to symptoms. Overall drop-outs not reported	Not reported, although compliance was monitored	Group A: adverse effects "generally mild (mostly anticholinergic symptoms and mild orthostatic hypotension) and did not require reduction of dosage" Group B: "no significant side effects"		

Appendix E1. Trials of Acetaminophen Included in the APS/ACP Review

Author, Year, Title	Purpose of Study	Study Design	Inclusion Criteria	Exclusion Criteria	Number of Treatment and Control Subjects (number approached, number eligible, number enrolled)
Wiesel,1980 Acute low back pain: an objective analysis of conservative therapy.	To analyze roles of bed rest, anti-inflammatory and analgesic medication in treatment of lumbago, measuring effect on pain relief and return to full daily activity.	Prospective randomized trial	No previous back problem. Results of neurological examination, straight leg raising test and lumbosacral spine roentgenograms within normal limits.	Not reported	Number approached and eligible not reported 200 enrolled, 80 in bed rest part of study, 45 in anti-inflammatory drug part, and 75 in analgesic medication part.

Appendix E1. Trials of Acetaminophen Included in the APS/ACP Review

Author, Year, Title	Subject Age, Gender, Diagnosis	Country and Setting	Sponsor	Measures
Wiesel,1980 Acute low back pain: an objective analysis of conservative therapy.	Mean age: 23 years Female gender: none Race: not reported Duration of pain and baseline pain intensity not reported Diagnosis: acute back strain - nonradiating LBP	US army hospital and outpatient clinic. Subjects were combat trainees.	Not reported	Vital statistics recorded on back study sheet completed by physician. Pain: patient told by technician on 1st day that pain rating was 10. On subsequent days, patient asked to quantify pain in points compared to previous day. Classification into mild (subjective back pain but no objective findings), moderate (limited range of spinal motion and paravertral muscle spasm as well as pain) and severe (inability to straighten spine and difficulty walking) pain categories.

Appendix E1. Trials of Acetaminophen Included in the APS/ACP Review

Author, Year, Title	Type of Intervention	Results
Wiesel,1980 Acute low back pain: an objective analysis of conservative therapy.	1. Bed rest: not included here 2. Anti-inflammatory drugs: all patients admitted to hospital for bed rest. Group A: 1 acetaminophen tablet 2x day. Group B: 625 mg aspirin 4x/day. Group C: 100mg phenylbutazone 4x/day for 1st 5 days. 3. Analgesic medication: Group A: bed rest + 1 acetaminophen. Group B: bed rest + codeine 60 mg 4x/day. Group C: oxycodone + aspirin, 1 tablet 4x/day	Only results of drug comparisons reported here. 2. Group A vs. Group B vs. Group C: no significant difference among treatments for pain or return to work. Pain (average subjective pain points for mild, moderate and severe): 41.40 vs. 27.07(0 patients in severe pain) vs. 49.40 3. Group A vs. Group B vs. Group C: no significant difference among treatments in time to return to work. Number of days before return to full activity: 5.6 vs. 5.24 vs. 5.6

Appendix E1. Trials of Acetaminophen Included in the APS/ACP Review

Author, Year, Title	Duration of Followup	Loss to Followup	Compliance to Treatment	Adverse Events and Withdrawals Due To Adverse Events	Quality Rating	Comments
Wiesel,1980 Acute low back pain: an objective analysis of conservative therapy.	15 days of treatment	Not reported	Not reported	Not reported		Incomplete and confusing report of results. No standardized measures of pain.

Please see Appendix C. Included Studies for full study references.

Appendix E2. Randomized Controlled Trials of Acetaminophen

Author, Year	Country Number of Centers and Setting	Inclusion Criteria	Number Randomized, Analyzed Attrition	Intervention	Study Participants	Duration of Pain (acute, subacute, chronic)	Outcome Measures
Williams, 2014	Australia Multicenter	New episode of acute low back pain (<6 weeks duration with no pain in prior month) with or without leg pain of at least moderate intensity (based on item 7 of SF-12) Exclude: Suspected serious spinal pathology, use of full doses of an analgesic, spinal surgery in past 6 months, contraindication to acetaminophen, use of psychotropic drugs for a disorder judged to prevent reliable recording of study information, pregnant or planning pregnancy	Randomized: 1652 Analyzed: 1643 Attrition: 2.8% (46/1652)	A: Acetaminophen: 665 mg 2 tabs po q6-8 hours (6 tabs/day) + placebo 1-2 tabs po q4-6 hours prn (up to 8 tabs/day) (n=550) B: Acetaminophen: Placebo 2 tabs po q6-8 hours (6 tabs/day) + 500 mg 1-2 Tabs po q4-6 hours prn (up to 8 tabs/day) (n=546) C: Placebo: Placebo 2 tabs po q6-8 hours (6 tabs/day) + placebo 1-2 tabs po q4-6 hours prn (up to 8 tabs/day) (n=547) Medications taken until recovery or for 4 weeks	Mean age: 44 vs. 45 vs. 45 years Female: 48% vs. 47% vs. 45% Race: Not reported Baseline pain (mean, 0-10 NRS): 6.3 vs. 6.3 vs. 6.2 Baseline RDQ (mean, 0-24): 3.5 vs. 3.6 vs. 3.7 Pain below knee: 20% vs. 21% vs. 18%	<6 weeks; mean duration 10 vs. 10 vs. 10 days	

Appendix E2. Randomized Controlled Trials of Acetaminophen

Author, Year	Duration of Followup	Results (list results for acute, subacute, and chronic separately)	Adverse Events Including Withdrawals	Funding Source	Quality	Comments
Williams, 2014	12 weeks	A vs. B vs. C Pain (mean, 0-10): 3.7 vs. 3.8 vs. 3.6 at w 1, 2.6 vs. 2.6 vs. 2.5 at w 2, 1.7 vs. 1.8 vs. 1.7 at w 4, 1.2 vs. 1.3 vs. 1.3 at w 12 RDQ (mean, 0-24): 7.7 vs. 8.0 vs. 8.3 at w 1, 5.2 vs. 5.4 vs. 5.3 at w 2, 3.2 vs. 3.5 vs. 3.3 at w 4, 2.4 vs. 2.6 vs. 2.4 at w 12 Patient Specific Functional Scale (mean, 0-10): 6.2 vs. 6.1 vs. 6.2 at w 1, 7.3 vs. 7.2 vs. 7.4 at w 2, 8.2 vs. 8.1 vs. 8.2 at w 4, 8.7 vs. 8.7 vs. 8.7 at w 12 Global change (mean, -5 to +5): 2.1 vs. 2.0 vs. 2.1 at w 1, 2.8 vs. 2.7 vs. 2.8 at w 2, 3.4 vs. 3.4 vs. 3.5 at w 4, 3.8 vs. 3.7 vs. 3.8 at w 12 Sleep quality "fairly bad" or "very bad": 28% (143/514) vs. 26% (129/501) vs. 26% (127/496) at w 1, 17% (85/508) vs. 18% (88/495) vs. 17% (85/497) at w 2, 12% (59/507) vs. 11% (57/500) vs. 10% (52/503) at w 4, 11% (54/506) vs. 11% (55/503) vs. 8.6% (44/514) at w 12 SF12 Physical score (mean, 0-100): 50 vs. 50 vs. 51 at w 4, 55 vs. 55 vs. 55 at w 12 SF12 Mental score (mean, 0-100): 44 vs. 44 vs. 44 at w 4, 46 vs. 46 vs. 45 at w 12 No differences in use of concomitant medications or health services or hours absent from work Days to recovery (median, days): 17 vs. 17 vs. 16 Satisfied with treatment: 76% (365/478) vs. 72% (342/472) vs. 73% (335/458)	A vs. B vs. C Serious adverse events: 1% (5/550) vs. 1% (4/546) vs. 1% (5/547)	National Health and Medical Research Council of Australia and GlaxoSmithKline		

Please see Appendix C. Included Studies for full study references.

Appendix E3. Trials of NSAIDs Included in the APS/ACP Review

Author, year, title	Purpose of study	Databases searched, date of last search	Number of studies	Types of studies included/limitations of primary studies	Methods for rating methodological quality of primary studies
van Tulder, 2000 Nonsteroidal anti-inflammatory drugs for low back pain. A systematic review within the framework of the Cochrane Collaboration Back Review Group (also published as a Cochrane review)	Evaluate the effects of NSAIDs for low back pain and the comparative effectiveness of different NSAIDs	MEDLINE, EMBASE, and Cochrane Controlled Trials Register (through 9/98). Languages: English, Dutch and German.	51	RCTs and double-blind controlled trials. Limitations: 16/51 studies had >=6/11 quality score (threshold for high quality). 4 studies of chronic LBP. Infrequent measures to avoid co interventions. Small sample sizes, and pooling frequently not possible because of methods by which data reported, or not reported.	11-criteria quality rating instrument adapted from previous systematic review on NSAIDs (Koes 1997)

Appendix E3. Trials of NSAIDs Included in the APS/ACP Review

Author, year, title	Methods for synthesizing results of primary studies	Number of patients (treatment and control)	Interventions
van Tulder, 2000 Nonsteroidal anti-inflammatory drugs for low back pain. A systematic review within the framework of the Cochrane Collaboration Back Review Group (also published as a Cochrane review)	Quantitative analysis for clinically homogeneous studies. Qualitative analysis for heterogeneous studies or if unable to perform statistical pooling because data not available, using best evidence methods	6057	NSAIDs

Appendix E3. Trials of NSAIDs Included in the APS/ACP Review

Author, year, title	Results: Acute and subacute	Results: Chronic	Results: Mixed acute and chronic or not clearly specified	Adverse events
van Tulder, 2000 Nonsteroidal anti-inflammatory drugs for low back pain. A systematic review within the framework of the Cochrane Collaboration Back Review Group (also published as a Cochrane review)	NSAID vs. placebo (9 RCTs): Conflicting evidence for pain intensity: not significantly different (pooled standardized mean difference -0.53, 95% CI -2.74-1.69) for 3 RCTs in which pooling could be performed. For 4 other RCTs reporting pain as an outcome, 2 reported no differences, and 2 NSAID superior. Global improvement favors NSAID (6 RCTs had RR 1.24, 95% CI 1.10 to 1.41). Additional analgesic use favors NSAID (3 studies had RR 1.29, 95% CI 1.05-1.57). NSAID vs. acetaminophen (5 RCTs): Conflicting evidence that NSAIDs are more effective NSAID vs. opioids or muscle relaxants (6 RCTs): Moderate evidence that NSAIDS are not more effective than other drugs for acute LBP NSAID vs. bed rest (2 RCTs): Conflicting evidence NSAID vs. manipulation or PT (2 RCTs): No differences NSAID vs. NSAID (24 RCTs): Insufficient evidence to judge comparative efficacy for any two specific NSAIDs NSAID vs. NSAID + muscle relaxant (3 RCTs): 2 RCTs found combination superior, but not statistically significant NSAID vs. NSAID + B vitamin (3 RCTs): Conflicting evidence (3 RCTs found combination superior, but not	NSAID vs. acetaminophen: Limited evidence that NSAIDs are more effective (1 high quality RCT) Insufficient evidence for chronic LBP (4 RCTs, all evaluating different comparisons)		NSAID vs. placebo: RR 0.83 (95% CI 0.64-1.08) NSAID vs. NSAID (24 RCTs): No clear differences

Please see Appendix C. Included Studies for full study references.

Appendix E4. Data Abstraction of Systematic Reviews of NSAIDs

Author, Year	Comparison	Databases Searched, Date of Last Search	Number and Type of Studies	Interventions and Number of Patients	Methods for Rating Methodological Quality of Primary Studies
Roelofs 2008	NSAIDs vs placebo NSAID vs NSAID NSAID vs other active treatments	MEDLINE, EMBASE, Cochrane Library through 2007	65 trials (RCT and controlled clinical trials) NSAID vs placebo (16 trials); NSAIDs vs other medications (9 trials) or passive physical modalities (4 trials); NSAIDs vs NSAIDs (33 trials); other studies included in other intervention sections (NSAIDs + SMR vs NSAIDs, 3 trials; NSAIDs vs acetaminophen, 7 trials); other studies outside the scope of this review (NSAIDs + B vitamins vs NSAIDs alone, 3 trials) Acute low back pain (25 trials), chronic low back pain (9 trials) mixed or unclear low back pain population (31 trials)	A. NSAIDs (nonselective and selective) B. Other medications C. Other active interventions (i.e. passive physical modalities) D. Placebo Total n=11,237	Cochrane Back Review Group Criteria (2003)

Appendix E4. Data Abstraction of Systematic Reviews of NSAIDs

Methods for Rating Methodological Quality of Primary Studies	Methods for Synthesizing Results of Primary Studies	Results	Adverse Events	Quality
Cochrane Back Review Group Criteria (2003)	Quantitative analysis of (weighted) mean difference used fixed effects model when possible; qualitative analysis for other outcomes	NSAIDs versus placebo, acute LBP: Pain: VAS (100 mm) ≤3 weeks: 4 studies, WMD -8.39, 95% CI -12.68 to -4.10 VAS (100 mm) from baseline: LBP without sciatica, 3 studies, WMD -7.69, 95% CI -12.08 to -3.30 LBP with sciatica, 2 studies, WMD -0.16, 95% CI -11.92 to 11.59 Mixed population, 1 study, WMD -23.4, 95% CI -43.67 to -3.13 NSAIDs versus placebo, chronic LBP: Pain: VAS (100 mm) ≤12 weeks: 4 studies, WMD -12.40, 95% CI -15.53 to -9.26 COX-2 versus traditional NSAID, Acute LBP, VAS (100 mm): 3 studies, WMD -1.17, 95% CI -4.67 to 2.33 Chronic LBP, VAS (100 mm): 1 study, WMD 2.0, 95% CI -1.92 to 5.92	Proportion of patients experiencing side effects: NSAIDs versus placebo, acute LBP, followup ≤3 weeks: 10 studies, RR 1.35, 95% CI 1.09 to 1.68 NSAIDs versus placebo, chronic LBP, followup up ≤12 weeks: 4 studies, RR: 1.24, 95% CI 1.07 to 1.43 COX-2 versus traditional NSAID: Proportion of patients experiencing side effects: 4 studies, RR 0.83, 95% CI 0.70 to 0.99 Proportion of patients experiencing gastrointestinal side effects: 1 study, RR 0.88 95% CI 0.48 to 1.64	Good

Please see Appendix C. Included Studies for full study references.

Appendix E5. Data Abstraction of Randomized Controlled Trials of NSAIDs

Author, Year	Country Number of Centers and Setting	Inclusion Criteria	Number Randomized, Analyzed Attrition	Intervention	Study Participants	Duration of Pain (acute, subacute, chronic)
Herrmann, 2009	Germany Multicenter Outpatient	18-70 years, sciatica or lumbo-sciatica with onset within the last 72 hours with any previous attacks had to be resolved at least 3 months earlier.	Randomized: 171 Analyzed: 171 Attrition: 0	A: Lornoxicam 8mg tablets, with 16 mg loading dose on day 1, then 8mg after 8 hours; 8 mg twice per day on days 2-4; 8 mg on day 5 B: Diclofenac: 50 mg twice per day on days 1 and 5; 50mg three times per day on days 2-4. C: Placebo capsules in LNX or diclofenac blister packs Day 5 treatment was optional	Mean age: 51.8 vs. 48.9 vs. 48.4 Gender, male: 56% vs. 53% vs. 58% Race, Caucasian: 91% vs. 93% vs. 98% Pain etiology: Sciatica or lumbo-sciatica	Acute pain, total duration of previous low back pain: 53.8 vs. 44.1 vs. 53.9 months
Majchrzycki, 2014	Poland Single center Outpatient clinic	40-60 years old, Pain lasting longer than 7 weeks, VAS1 and VAS2 scores ≥ 25mm of 100mm, no NSAID or strong analgesic therapy during the last 3 months	Randomized: 59 Analyzed: 54 Attrition: 5	A. Deep tissue massage + NSAID (n=26) B. Deep tissue massage (n=28)	Mean age: 50.8 vs. 52.6 Gender, female: 13/26 vs. 13/28 Race: NR Chronic pain: 100% Baseline pain: NR Baseline function: NR QOL: NR	Subacute duration, weeks: 11.9±3.9 vs. 10.8±2.4

Appendix E5. Data Abstraction of Randomized Controlled Trials of NSAIDs

Author, Year	Duration of Followup	Results	Adverse Events Including Withdrawals	Funding Source	Quality
Herrmann, 2009	5 days	A vs. B vs. C Pain intensity difference, mm: 3 hours: -21.0 vs. -18.7 vs. -15.3, p≤0.05 for A vs. C 4 hours: -22.0 vs. -21.5 vs. -14.8, p≤0.05 for A vs. C 6 hours: -20.5 vs. -22.4 vs. -14.9, p≤0.05 for A vs. C 8 hours: -22.0 vs. -24.1 vs. -13.7, p≤0.05 for A vs. C Sum of time-weighted pain intensity difference, mm x minute: 0-4 hours: -4020 vs. -3879 vs. -2901, p≤0.05 for A vs. C 0-6 hours: -6486 vs. -6358 vs. -4713, p≤0.05 for A vs. C 0-8 hours: -9125 vs. -8833 vs. -6257, p≤0.05 for A vs. C Pain Relief (mm): 3 hours: 30.1 vs. 30.8 vs. 26.6 4 hours: 31.7 vs. 33.9 vs. 26.6 6 hours: 31.1 vs. 34.3 vs. 26.1 8 hours: 31.9 vs. 35.6 vs. 23.9, p≤0.05 for A vs. C Peak pain intensity difference, A vs. C: -27.9 mm vs. -19.9 mm, p=0.01 Time to peak pain intensity difference, A vs. C: 243 vs. 240 minutes, no difference Peak pain relief, A vs. C : 38.0 mm vs. 31.1 mm, p=0.05 Time to peak pain relief: no difference Start of peak pain relief: no difference End of peak pain relief: no difference Duration of peak pain relief: no difference	A vs. B vs. C Withdrawals: 4 vs. 2 vs. 1 Withdrawals due to AEs: 2 vs. 1 vs. 0 Serious AEs: 0 vs. 2 vs. 0 Nonserious AEs: 11 vs. 7 vs. 7	Nycomed Pharma Austria, Merckle GmbH Ulm, Germany	Fair
Majchrzycki, 2014	2 weeks	Difference scores, no significantly different results between groups on: Roland-Morris questionnaire: 21.2 vs. 16.1 Oswestry disability index: 24.7 vs. 19.6 VAS1: pain intensity during resting: 16.5 vs. 13.9 VAS2: pain intensity during motion: 3.2 vs. 3.4 VAS3: pain intensity during mobility of the aching area of the spine: 4.8 vs. 8.2	Withdrawals: 3 vs. 2 Withdrawals due to AEs: NR Serious AEs: NR Nonserious AEs: NR	Not reported	Fair

Appendix E5. Data Abstraction of Randomized Controlled Trials of NSAIDs

Author, Year	Country Number of Centers and Setting	Inclusion Criteria	Number Randomized, Analyzed Attrition	Intervention	Study Participants	Duration of Pain (acute, subacute, chronic)
Shirado, 2010	Japan Multicenter Orthopedic surgeon clinics	Age 20-64, nonspecific chronic low back pain of more than 3 months duration	Randomized: 201 Analyzed: 193 Attrition: 8	A: NSAIDs: loxoprofen sodium, 60 mg tablet 3 times daily; diclofenac sodium, 25 mg tablet 3 times daily; or zaltoprofen, 80 mg tablet 3 times daily B: Exercise: medical professionals at each clinic gave instruction of the exercise. 2 types of exercise: trunk strengthening and stretching. 2 sets of 10 repetitions of each exercise per day were encouraged.	Mean Age: 42.5 vs. 42.0 Female: 59% vs. 52% Race: NR Pain type: All chronic pain Baseline pain: VAS (0-10): 3.8 vs. 3.5 QOL scores: RDQ (0-24): 3.7 vs. 3.0 JLEQ score (0-120): 21.8 vs. 20.5	≥ Subacute duration, details not reported

Appendix E5. Data Abstraction of Randomized Controlled Trials of NSAIDs

Author, Year	Duration of Followup	Results	Adverse Events Including Withdrawals	Funding Source	Quality
Shirado, 2010	12 months	Baseline to 8 week change ratio: Pain: VAS: -0.35 vs. -0.44, p=0.332 Function: Finger-floor distance: 0.00 vs. -0.09, p=0.112 RDQ: -0.47 vs. -0.72, p=0.023 JLEQ: -0.44 vs. -0.58, p=0.021	NR	No commercial sponsor	Good

Please see Appendix C. Included Studies for full study references.

Appendix E6. Trials of Opioids and Tramadol Included in the APS/ACP Review

Author, Year, Title	Purpose of Study	Study Design	Inclusion Criteria	Exclusion Criteria	Number of Treatment and Control Subjects (number approached, number eligible, number enrolled)
Allan, 2005 Transdermal fentanyl versus sustained release oral morphine in strong-opioid naïve patients with chronic low back pain	To assess the efficacy and safety of titrated transdermal fentanyl versus oral long-acting morphine in patients with chronic low back pain not recently on regular strong opioids	Randomized controlled trial	Adults with chronic low back pain requiring regular strong opioids	Receipt of more than 4 doses of strong opioids in a week in the 4 weeks before the study, high risk of ventilatory depression or intolerance to study drugs, prior alcohol or substance abuse, presence of other chronic pain disorders, or life-limiting illness	Not reported Not reported 683 enrolled
Baratta, 1976 A double-blind comparative study of carisoprodol, propoxyphene, and placebo in the management of low back syndrome	To compare efficacy of carisoprodol, propoxyphene, and placebo in patients with low back pain	Randomized controlled trial	Patients with acute or chronic low back syndrome (other criteria not specified)	Not specified	Not reported Not reported 105

Appendix E6. Trials of Opioids and Tramadol Included in the APS/ACP Review

Author, Year, Title	Subject Age, Gender, Diagnosis	Country and Setting	Sponsor	Measures
Allan, 2005 Transdermal fentanyl versus sustained release oral morphine in strong-opioid naïve patients with chronic low back pain	Avg. 54.0 years 61% female Race: not reported 35% nociceptive 4% neuropathic 46% nociceptive and neuropathic 3% nociceptive with psychologic factors 4% neuropathic with psychologic factors 83% mechanical low back pain 8% inflammatory 39% trauma/surgery 1% metabolic 3% other Prior opioid use not reported Pain duration average 124.7 months	Europe Multicenter (number of sites not clear) Clinic setting not described	Janssen Pharmaceutica. One author employed by Janssen.	**Pain relief** VAS (0-100) assessed at baseline and every week **Bowel function** PAC-SYM baseline, day 15, day 29, and monthly **Quality of Life** (SF-36) baseline, day 29, then monthly or 3-monthly **Back pain at rest, on movement, during day, and at night** scale not specified **Global assessment** investigator assessment on 3-point scale (deteriorated, unchanged, improved) **Rescue medication use** **Work status** number of days lost to work
Baratta, 1976 A double-blind comparative study of carisoprodol, propoxyphene, and placebo in the management of low back syndrome	Avg. 37 years Female gender: 18% vs. 31% vs. 21% nonwhite: Race: 9% vs. 22% vs. 10% Underlying conditions: lumbosacral sprain, cervical sprain, sacroiliac sprain, thoraco-lumbar sprain, thoraco-spinalis sprain Baseline severity and duration not reported Previous opioid use not reported	US Single center Family practice clinic	Not stated	Functional measurements: flexion, extension, rotation, etc. Pain symptoms: active and passive on 0 (absent) to 3 (very severe) scale Other symptoms: discomfort, stiffness and anxiety on 0 (absent) to 3 (very severe) Sleep patterns: early and middle insomnia and total hours of sleep Global improvement: rated by investigator using 3-point scale ("satisfactory", "mild", or "no relief") Assessments completed at baseline and 2x/week

Appendix E6. Trials of Opioids and Tramadol Included in the APS/ACP Review

Author, Year, Title	Type of Intervention	Results	Duration of Followup
Allan, 2005 Transdermal fentanyl versus sustained release oral morphine in strong-opioid naïve patients with chronic low back pain	A: Transdermal fentanyl (titrated from 25 mcg/hr) (Mean dose 57 mcg/h) B: Long acting morphine (titrated from 30 mg q 12 hrs) (Mean dose 140 mg) 13 months	Fentanyl (A) vs. Long acting morphine (B) **Pain score** (mean, 0-100 VAS) at 56 weeks (N=608): 56.0 (A) vs. 55.8 (B) **Severe pain at rest (per protocol analyses, n=248 and 162)** 22/248 (9%) (A) vs. 20/162 (12%) (B), p=0.030 (no significant differences in ITT analysis, but data not provided) **Severe pain on movement (per protocol)** 70/248 (28%) (A) vs. 43/162 (27%) (B), p=0.61 **Severe pain during the day (per protocol)** 48/248 (19%) (A) vs. 40/162 (25%) (B), p=0.385 **Severe pain at night (per protocol)** 25/248 (10%) (A) vs. 26/162 (16%) (B), p=0.003 (no significant differences in ITT analysis, but data not provided) **Rescue strong opioids use** 154/296 (52%) (A) vs. 154/291 (53%) (B) **Quality of life (SF-36)** No differences between interventions **Loss of working days** No differences between interventions	13 months
Baratta, 1976 A double-blind comparative study of carisoprodol, propoxyphene, and placebo in the management of low back syndrome	A: Propoxyphene 65 mg QID B: Carisoprodol 350 mg QID C: Placebo 14 days	A vs. B vs. C (mean improvement from baseline) Pain on active movement (0 to 3 scale): 0.9 vs. 0.8 vs. 0.4 (NS) Pain on passive movement (0 to 3 scale): 1.0 vs. 0.8 vs. 0.5 (NS) Discomfort (0 to 3 scale): 0.3 vs. 0.8 vs. -0.1 (p=0.01 for B vs. C) Stiffness (0 to 3 scale): 0.4 vs. 1.0 vs. -0.1 (p=0.01 for A vs. B and p<0.01 for B vs. C) Anxiety (0 to 3 scale): 0.8 vs. 1.0 vs. 0.4 (NS) Difficulty falling asleep: 0.8 vs. 1.0 vs. 0.2 (p<0.01 for A or B vs. C) Number of times awakened during night: 0.9 vs. 1.3 vs. 0.8 (p=0.02 for B vs. C) Total hours of sleep: 0.6 vs. 0.6 vs. 0.3 (NS) Global improvement "satisfactory": 7/32 (22%) vs. 19/33 (58%) vs. 4/29(14%) (p=0.02 for A vs. B, p<0.01 for B vs. C)	10-16 days

Appendix E6. Trials of Opioids and Tramadol Included in the APS/ACP Review

Author, Year, Title	Loss to Followup	Compliance to Treatment	Adverse Events and Withdrawals Due To Adverse Events	Quality Rating	Comments
Allan, 2005 Transdermal fentanyl versus sustained release oral morphine in strong-opioid naïve patients with chronic low back pain	48% in transdermal fentanyl vs. 53% in oral long-acting morphine arms did not complete trial	Terminated from trial due to noncompliance: 3/338 (<1%) vs. 6/342 (2%)	Transdermal fentanyl (n=338) vs. long-acting oral morphine (n=342) Any adverse event: 87% vs. 91% Constipation (ITT): 176/338 (52%) vs. 220/338 (65%) (p<0.05) Nausea: 54% vs. 50% Vomiting: 29% vs. 26% Somnolence: 17% vs. 30% Dizziness: 25% vs. 24% Fatigue: 17% vs. 14% Pruritus: 15% vs. 20% Application site reactions: 9% in transdermal fentanyl group Deaths: None Addiction: None reported Use of laxatives: 177/336 (53%) vs. 221/336 (66%) (p<0.001) Use of antiemetics/anticholinergics: 38% vs. 36% Use of antihistamines: 21% vs. 12% (p=0.002) Withdrawal due to adverse events: 125/335 (37%) vs. 104/337 (31%) (p=0.098)		Open-label, and intention-to-treat results not reported for some outcomes
Baratta, 1976 A double-blind comparative study of carisoprodol, propoxyphene, and placebo in the management of low back syndrome	11/105 (10%) 94 analyzed	Not clear	No adverse reactions reported		High number of patients screened and enrolled in titration phase not enrolled into randomized phase

Appendix E6. Trials of Opioids and Tramadol Included in the APS/ACP Review

Author, Year, Title	Purpose of Study	Study Design	Inclusion Criteria	Exclusion Criteria	Number of Treatment and Control Subjects (number approached, number eligible, number enrolled)
Gostick, 1989 A comparison of the efficacy and adverse effects of controlled release dihydrocodeine and immediate release dihydrocodeine in the treatment of pain in osteoarthritis and chronic back pain	To compared the efficacy of long- and short-acting dihydrocodeine for low back pain	Randomized controlled trial with crossover	Chronic back pain due to osteoarthritis of weight bearing joints or chronic back pain	Pregnancy, lactation, contraindication to study medication	Not reported Not reported 61
Hale , 1997 Efficacy of 12 hourly controlled-release codeine compared with as required dosing of acetaminophen plus codeine in patients with chronic low back pain	To compare scheduled, fixed-dose long-acting codeine with titrated short-acting codeine (both with acetaminophen) in patients with chronic low back pain	Randomized controlled trial	Patients with chronic low back pain deemed by investigators to be in need of opioid or fixed combination codeine analgesics for control of stable mild to moderately severe pain	18 years and older; no medical contraindication to the use of codeine or acetaminophen	Not reported Not reported 104

Appendix E6. Trials of Opioids and Tramadol Included in the APS/ACP Review

Author, Year, Title	Subject Age, Gender, Diagnosis	Country and Setting	Sponsor	Measures
Gostick, 1989 A comparison of the efficacy and adverse effects of controlled release dihydrocodeine and immediate release dihydrocodeine in the treatment of pain in osteoarthritis and chronic back pain	Avg. 52 years 56% female Race not reported Osteoarthritis 45% Chronic back pain 55% Pain duration not reported	Canada Multicenter Number and types of clinics not specified	Not specified. One author employed by Napp Pharmaceutical, maker of long acting dihydrocodeine.	**Pain intensity:** Scale not described. Mean and Maximum scores collected daily **Rescue drug use:** average number of doses used per day **Global efficacy:** Scale not described. **Preference:** Percent preferring each treatment arm at end of study.
Hale , 1997 Efficacy of 12 hourly controlled-release codeine compared with as required dosing of acetaminophen plus codeine in patients with chronic low back pain	Avg. 52 years 54% female Race not reported Back pain due to Arthritis (33%) mechanical injury (45%) Prior opioid use mentioned but not reported in detail. Pain duration not reported.	US 1 or 2 centers	Purdue Frederick sponsored study. 1 author (corresponding) employed by Purdue.	**Pain intensity** recorded at baseline and four times a day (0-3 categorical, no pain-severe) **Rescue medication use:** number of doses used.

Appendix E6. Trials of Opioids and Tramadol Included in the APS/ACP Review

Author, Year, Title	Type of Intervention	Results	Duration of Followup
Gostick, 1989 A comparison of the efficacy and adverse effects of controlled release dihydrocodeine and immediate release dihydrocodeine in the treatment of pain in osteoarthritis and chronic back pain	A: Long acting dihydrocodeine (titrated, 60-120 mg BID) B: Short acting dihydrocodeine (titrated, 30-60 mg QID) Average dose not reported 2 weeks initial intervention with 2 weeks crossover	Long acting Dihydrocodeine (A) vs. short acting Dihydrocodeine (B) **Pain intensity (daily average):** 1.75 (A) vs. 1.80 (B); (p NS) **Pain intensity (maximum):** 2.48 (A) vs. 2.33 (B); (p NS) **Rescue drug use:** 1.54 (A) vs. 1.61 (B); (p NS) **Global efficacy:** no difference **Preference**: no difference	2 weeks each intervention
Hale , 1997 Efficacy of 12 hourly controlled-release codeine compared with as required dosing of acetaminophen plus codeine in patients with chronic low back pain	A: Long acting codeine (fixed) + acetaminophen B: Short acting codeine (titrated) + acetaminophen Mean dose opioid 200 mg/day (A) 71 mg/day (B) 5 days	Long acting Codeine + Acetaminophen (A) vs. short acting Codeine + Acetaminophen (B) **Pain intensity:** Daily Pain Intensity Differences Scores: 4.25 (A) vs. 2.0 (B) (p = 0.008) Pain Score Variation: increases 2.0 vs. 4.0 (p = 0.032) decreases 2.2 vs. 4.6 (p = 0.006) **Rescue medication use:** Night: 3.0 vs. 4.0 (p=0.032) Day: 1.01 vs. 1.53 (p = 0.018)	5 days

Appendix E6. Trials of Opioids and Tramadol Included in the APS/ACP Review

Author, Year, Title	Loss to Followup	Compliance to Treatment	Adverse Events and Withdrawals Due To Adverse Events	Quality Rating	Comments
Gostick, 1989 A comparison of the efficacy and adverse effects of controlled release dihydrocodeine and immediate release dihydrocodeine in the treatment of pain in osteoarthritis and chronic back pain	16 (26%) 42 analyzed	Not reported	Long-acting dihydrocodeine vs. short-acting dihydrocodeine Bowel movement less frequently than once every two days: 23/42 (55%) vs. 21/44 (48%) Daily use of laxative: 1/41 (2.4%) vs. 3/42 (7.1%) Withdrawals due to adverse events: 16/61 (26%) overall, "no treatment differences" Other adverse events: Not reported ("no significant differences")		
Hale , 1997 Efficacy of 12 hourly controlled-release codeine compared with as required dosing of acetaminophen plus codeine in patients with chronic low back pain	23 (22%) 83 analyzed	Not reported	Long-acting codeine (fixed) plus acetaminophen vs. short-acting codeine (titrated) plus acetaminophen (rate of "serious" adverse events in brackets) Nausea: 16/52 (31%) [15%] vs. 9/51 (18%) [4%] Vomiting: 5/52 (10%) [8%] vs. 1/51 (2%) [2%] Constipation: 10/52 (19%) [2%] vs. 8/51 (16%) [0%] Dizziness: 9/52 (17%) [4%] vs. 2/51 (4%) [0%] Headache: 8/52 (15%) [0%] vs. 4/51 (8%) [4%] Somnolence: 5/52 (10%) [0%] vs. 2/51 (4%) [0%] Dyspepsia: 4/52 (8%) [4%] vs. 2/51 (4%) [2%] Dry mouth: 8/52 (15%) [0%] vs. 0/51 (0%) [0%] Pruritus: 3/52 (6%) [4%] vs. 2/51 (4%) [2%] Withdrawal due to adverse events: 13/53 (25%) vs. 4/51 (8%)		

Appendix E6. Trials of Opioids and Tramadol Included in the APS/ACP Review

Author, Year, Title	Purpose of Study	Study Design	Inclusion Criteria	Exclusion Criteria	Number of Treatment and Control Subjects (number approached, number eligible, number enrolled)
Hale, 1999 Efficacy and safety of controlled release versus immediate release oxycodone: randomized, double blind evaluation in patients with chronic back pain	To compare efficacy of scheduled long-acting oxydone with as-needed oxycodone in patients with chronic low back pain	Randomized controlled trial with crossover	Patients at least 18 years old with stable, chronic moderate-to-severe low back pain caused by nonmalignant conditions, on maximum doses of nonopioid analgesics, with or without opioids.	History of substance abuse Involved in litigation regarding back pain condition. Able to achieved stable analgesia within 10 days during titration phase.	Not reported Not reported 57
Hale, 2005 Efficacy and safety of oxymorphone extended release in chronic low back pain: results of a randomized, double-blind, placebo- and active-controlled phase III study	To compare efficacy and safety of long-acting oxymorphone and oxycodone in patients with chronic low back pain	Randomized double-blinded controlled trial with dose titration phase	18 to 75 years, moderate to severe low back pain for at least 15 days per month for past 2 months, stable dose of opioids for at least 3 days prior to enrollment	Fibromyalgia, multiple specified causes for back pain, malignancy, infection, neurologic dysfunction, psychiatric conditions, concomitant illness, history of drug or alcohol dependence, hypersensitivity to opioids, back surgery within 2 months or nerve/plexus block within 4 weeks, active or pending litigation	420 screened 330 underwent randomized titration 235 enrolled in stable dose intervention phase

Appendix E6. Trials of Opioids and Tramadol Included in the APS/ACP Review

Author, Year, Title	Subject Age, Gender, Diagnosis	Country and Setting	Sponsor	Measures
Hale, 1999 Efficacy and safety of controlled release versus immediate release oxycodone: randomized, double blind evaluation in patients with chronic back pain	Avg. 55 years 51% female Race not reported Back pain due to: 1) intervertebral disc disease 2) osteoarthritis. 88% (50/57) were on unspecified narcotics prior to study Pain duration not reported	Randomized trial Crossover US Multicenter (5) Rheumatology clinics and others	Purdue Pharma sponsored study. 4 authors employed by Purdue.	**Pain intensity** recorded in daily diary (0-3, categorical, none-severe) in morning, afternoon, evening, bedtime **Rescue drug use**: doses used per day
Hale, 2005 Efficacy and safety of oxymorphone extended release in chronic low back pain: results of a randomized, double-blind, placebo- and active-controlled phase III study	Median age=46 years 47% female Race not reported Median duration of low back pain 8 years "Most common" etiologies: degenerative disc disease, disc herniation, fracture, spondylosis, and spinal stenosis	US Multicenter Number and type of clinic setting not described	Endo Pharmaceuticals Inc and Penwest Pharmaceuticals Co	Pain intensity on VAS (0 to 100) at baseline and at 18 days and by 4 point categorical scale (0=none to 3=severe) Pain relief on VAS (0=no relief to 100=complete relief) Brief pain inventory Global evaluation on 5-point categorical scale (poor to excellent) Interference with normal activities on 100 point scale (0=no interference to 10=complete interference)

Appendix E6. Trials of Opioids and Tramadol Included in the APS/ACP Review

Author, Year, Title	Type of Intervention	Results	Duration of Followup
Hale, 1999 Efficacy and safety of controlled release versus immediate release oxycodone: randomized, double blind evaluation in patients with chronic back pain	A: Long acting oxycodone B: Short acting oxycodone Mean dose 40 mg/day 4-7 days followed by crossover	Long acting Oxycodone (A) vs. short acting Oxycodone (B) **Overall Pain intensity**: 1.2 (A) vs. 1.1 (B) (not significantly different). **Mean Pain Intensity**: Slight (A) vs. Slight (B) (not significantly different). **Rescue drug use**: 0.6 doses per day on average (no difference between treatment groups).	4-7 days followed by crossover
Hale, 2005 Efficacy and safety of oxymorphone extended release in chronic low back pain: results of a randomized, double-blind, placebo- and active-controlled phase III study	A: Long acting oxymorphone (titrated) (Mean dose 79.4 mg/day) B: Long acting oxycodone (titrated) (Mean dose 155 mg/day) C: Placebo 18 days	Long-acting oxymorphone (n=71) (A) vs. long-acting oxycodone (n=75) (B) vs. placebo (n=67) (C) **Pain Intensity (100 point VAS)** Compared to C differences were -18.21 and -18.55 for A and B (p=0.0001 for each comparison) **Pain Intensity** Categorical scale: Proportion rating pain intensity "none" or "mild" similar for A and B (around 14%) vs. C (45%) **Pain Relief** 56.8 vs. 54.1 vs. 39.1 **Pain Interference** A and B similar and superior to C for general activity, mood, normal work, relations with other people, and enjoyment of life (no difference for sleep and walking ability) **Global Assessment** "Good", "very good", or "excellent': 59% vs. 63% vs. 27% **Discontinuation due to treatment failure (treatment phase)** 20% vs. 16% vs. 57% **Discontinuation due to treatment failure (dose titration phase)** 7/166 (4.2%) vs. 4/164 (2.4%) **Rescue medication use** 13.8 vs. 14.7 mg/day after first 4 days	18 days

Appendix E6. Trials of Opioids and Tramadol Included in the APS/ACP Review

Author, Year, Title	Loss to Followup	Compliance to Treatment	Adverse Events and Withdrawals Due To Adverse Events	Quality Rating	Comments
Hale, 1999 Efficacy and safety of controlled release versus immediate release oxycodone: randomized, double blind evaluation in patients with chronic back pain	3/47 (6.4%) discontinued treatment	Not clear	Long-acting oxycodone vs. short-acting oxycodone (initial intervention) Nausea: 4/25 (16%) vs. 9/22 (41%), NS Constipation: 8/25 (32%) vs. 10/22 (45%), NS Dizziness: 4/25 (16%) vs. 2/22 (9%), NS Pruritus: 7/25 (28%) vs. 6/22 (27%), NS Somnolence: 3/25 (12%) vs. 4/22 (18%), NS Vomiting: 0/25 (0%) vs. 0/22 (0%), NS Headache: 2/25 (8%) vs. 2/22 (9%), NS Withdrawal due to adverse events (initial intervention + crossover phase): 2/47 (4%) vs. 1/47 (2%)		This paper reported results of two RCTs, one looking at patients with cancer, the other looking at patients with back pain of nonmalignant origin. The presented results are from the noncancer RCT. This study is the 10 day titration phase that preceded the study reported by Hale.
Hale, 2005 Efficacy and safety of oxymorphone extended release in chronic low back pain: results of a randomized, double-blind, placebo- and active-controlled phase III study	96/235 (41%) 213 analyzed	Not reported	Long-acting oxymorphone (A) vs. long-acting oxycodone (B) vs. placebo (C) Constipation: 39/110 (35%) vs. 32/111 (29%) vs. 12/108 (11%) Sedation: 19/110 (17%) vs. 22/111 (20%) vs. 2/108 (2%) Any adverse events: 85% vs. 86% vs. NR "Serious" adverse events possibly or probably related to study medication: 2 vs. 1 vs. NR (sample sizes not clear) Withdrawal (overall, titration phase): 53/166 (32%) vs. 42/164 (26%) Withdrawal (overall, treatment phase): 22/80 (28%) vs. 21/80 (26%) vs. 53/75 (71%) Withdrawal (adverse events, titration phase): 25/166 (15%) vs. 26/164 (16%) Withdrawal (adverse events, treatment phase): 2/80 (2.5%) vs. 4/80 (5.0%) vs. 5/75 (6.7%)		Nonequivalent dose of opioids given. Only long-acting morphine group had dose titrated for pain. Most statistical comparisons involved comparisons across all three groups (including naproxen only arm).

Appendix E6. Trials of Opioids and Tramadol Included in the APS/ACP Review

Author, Year, Title	Purpose of Study	Study Design	Inclusion Criteria	Exclusion Criteria	Number of Treatment and Control Subjects (number approached, number eligible, number enrolled)
Jamison, 1998 Opioid therapy for chronic noncancer back pain. A randomized prospective study	To compare efficacy and safety of long-acting morphine + short-acting oxycodone, short-acting oxycodone + NSAID, or NSAID alone for chronic back pain	Randomized controlled trial	Chronic back pain >6 months duration, age 25 to 65 years, average pain intensify >40 on scale of 0 to 100, unsuccessful response to traditional pain treatment	Cancer, acute osteomyelitis or acute bone disease, spinal stenosis and neurogenic claudication, nonambulatory, significant psychiatric history, pregnancy, treatment for drug or alcohol abuse, clinically unstable systemic illness, acute herniated disc within 3 months	48 screened Not reported 36 enrolled
Raber, 1999 Analgesic efficacy and tolerability of tramadol 100mg sustained-release capsules in patients with moderate to severe chronic low back pain	To investigate the analgesic efficacy, tolerability and therapeutic equivalence of newly developed tramadol sustained-release (SR) capsules vs. an immediate-release (IR) capsule in patients with moderate to severe chronic low back pain.	Randomized, multicenter, double-blind, parallel-group study	Aged 18 to 75 years, moderate to severe chronic low back pain >3 months due to chronic lumbar root irritation or compression or mechanical back pain	Metabolic bone disease, chronic inflammatory disease of the spinal column, arthritis related to enteropathies, patients with active cancer, clinical or radiological evidence of Paget's disease, acute nerve root compression or soft tissue damage, nonpharmacological therapy for low back pain, concomitant analgesics, cimetidine, carbamazepine, or monoamine oxidase inhibitors, pregnant or lactating	Number approached and eligible not reported 248 enrolled (125 sustained release, 122 immediate release)

Appendix E6. Trials of Opioids and Tramadol Included in the APS/ACP Review

Author, Year, Title	Subject Age, Gender, Diagnosis	Country and Setting	Sponsor	Measures
Jamison, 1998 Opioid therapy for chronic noncancer back pain. A randomized prospective study	Avg. 43 years 57% female Race not reported 39% failed back syndrome 25% myofascial pain syndrome 19% degenerative spine disease 14% radiculopathy 3% discogenic back pain Prior opioid use not reported Average pain duration 79 months	Randomized trial US Single center Pain clinic	Roxane Laboratories sponsored study (maker of long-acting morphine and short-acting oxycodone). Not clear if authors employed by Roxane.	**Pain Intensity:** timing not specified, Comprehensive Pain Evaluation Questionnaire **Functional status:** baseline and at end of treatment (SF-36) **Symptom checklist:** baseline and at end of treatment (Symptom Checklist-90) **Weekly activity record** at baseline and once a month **Medication diary** weekly **Overall helpfulness** during titration and at end of study (categorical scale, 0= no help, 10=extremely helpful)
Raber, 1999 Analgesic efficacy and tolerability of tramadol 100mg sustained-release capsules in patients with moderate to severe chronic low back pain	Gender, age, race: Not reported ('well-matched') Duration of pain not reported Severity of baseline pain about 53 in both groups	Germany, 22 centers	ASTA Medica AG, Frankfurt and Temmler Pharma GmbH, Marburg, Germany	Physical and lab work-up at baseline. Repeat labs at final visit Visual Analogue Scale (VAS): 100 mm VAS Sleep questionnaire Functional capacity score: 4-point scale (good to poor) Patient's global assessment of efficacy Adverse events: reported spontaneously or elicited by investigator

Appendix E6. Trials of Opioids and Tramadol Included in the APS/ACP Review

Author, Year, Title	Type of Intervention	Results	Duration of Followup
Jamison, 1998 Opioid therapy for chronic noncancer back pain. A randomized prospective study	A: Long acting morphine + short-acting oxycodone (titrated doses) + Naproxen B: Short-acting oxycodone (set dose) + Naproxen C: Naproxen Mean dose A: 41.1 mg morphine equivalent/day Mean dose B: Not reported, max 20 mg oxycodone/day Mean dose C: Not reported In all groups, max 1000 mg/day of naproxen 16 weeks	Long acting Morphine + short acting Oxycodone + naproxen (A) vs. short acting Oxycodone + naproxen (B) vs. naproxen (C) **Average pain (means, 0-100 VAS):** 54.9 vs. 59.8 vs. 65.5 **Current pain (means, 0-100 VAS):** 51.3 vs. 55.3 vs. 62.7 **Highest pain (means, 0-100 VAS):** 71.4 vs. 75.5 vs. 78.9 **Anxiety (means):** 11.2 vs. 15.0 vs. 31.6 **Depression (means):** 10.8 vs. 16.4 vs. 26.9 **Irritability (means):** 17.7 vs. 20.5 vs. 33.7 **Level of activity (means, 0-100 scale):** 49.3 vs. 49.3 vs. 51.5 **Hours of sleep (means):** 5.9 vs. 5.9 vs. 6.1	16 weeks
Raber, 1999 Analgesic efficacy and tolerability of tramadol 100mg sustained-release capsules in patients with moderate to severe chronic low back pain	A: Tramadol sustained release 100 mg twice a day B: Tramadol immediate release 50 mg four times a day 3 weeks intervention Additional tramadol sustained release 100 mg twice daily allowed if pain uncontrolled after 1 week	Tramadol sustained-release versus tramadol immediate-release Pain relief, improvement in VAS (0 to 100): -25 vs. -25 for per-protocol analysis; ITT results stated as similar but data not reported Functional assessment 'without pain' or 'slight pain possible': >80% in both intervention groups for putting on jacket, putting on shoes, and climbing/descending stairs No awakenings due to low back pain: 41% vs. 47% Global assessment 'good' or 'moderately good': 80% (84/105) vs. 81% (80/99) Global assessment 'good': 47% (49/105) vs. 46% (45/99)	9 days

Appendix E6. Trials of Opioids and Tramadol Included in the APS/ACP Review

Author, Year, Title	Loss to Followup	Compliance to Treatment	Adverse Events and Withdrawals Due To Adverse Events	Quality Rating	Comments
Jamison, 1998 Opioid therapy for chronic noncancer back pain. A randomized prospective study	3 (8.3%) 36 analyzed	Not reported	Long-acting morphine + short-acting oxycodone + naproxen vs. short-acting oxycodone + naproxen vs. naproxen (proportion reported weekly, sample sizes not clear) Dry mouth: 35% vs. 26% vs. 19% Drowsiness: 37% vs. 22% vs. 15% Headache: 32% vs. 20% vs. 15% Constipation: 30% vs. 18% vs. 10% Nausea: 31% vs. 14% vs. 5% Itching: 15% vs. 15% vs. 9% Dizziness: 6% vs. 19% vs. 9% Muddled thinking: 0% vs. 1.4% vs. 3% Withdrawal due to adverse events: 1/11 (9.1%) vs. 2/13 (15%) vs. 0/12 (0%)		Groups received different rescue medications. Not clear if rescue medication was blinded as well.
Raber, 1999 Analgesic efficacy and tolerability of tramadol 100mg sustained-release capsules in patients with moderate to severe chronic low back pain	44/248 (18%) of enrolled patients withdrew or excluded from analysis due to protocol violations	SR: 1/125 withdrew due to lack of compliance 17 others (group not specified) did not comply	Tramadol sustained-release vs. tramadol immediate-release Withdrawal due to adverse events: 9.6% (12/125) vs. 8.2% (10/122) Headache: 18% vs. 29% (p=0.071) Nausea: 11% vs. 21% (p=0.038) Tolerability 'good' or 'moderately good': 78% vs. 70%		

Appendix E6. Trials of Opioids and Tramadol Included in the APS/ACP Review

Author, Year, Title	Purpose of Study	Study Design	Inclusion Criteria	Exclusion Criteria	Number of Treatment and Control Subjects (number approached, number eligible, number enrolled)
Salzman, 1998 Can a controlled release oral dose form of oxycodone be used as readily as an immediate release form for the purpose of titrating to stable pain control?	To compare titrated long-acting and short-acting oxycodone for chronic low back pain	Randomized controlled trial	18 years or older, chronic stable moderate to severe back pain despite analgesic therapy with or without opioids.	Contraindication to opioid history of substance abuse Unable to discontinue nonstudy narcotic Current oxycodone dose >80 mg/day Titration to 80 mg without achieving pain control.	Not reported Not reported 57
Sorge, 1997 Comparison of the analgesic efficacy and tolerability of tramadol 100 mg sustained-release tablets and tramadol 50 mg capsules for the treatment of chronic low back pain	To compare the efficacy and tolerability of sustained-release and immediate-release tramadol in patients with chronic low back pain	Double-blind, randomized controlled trial	Moderate to severe low back pain of at least 3 months on unchanged nonpharmacological therapy for at least 3 weeks	Primary inflammatory etiology of low back pain, tumor or metastases, psychiatric disease, pension or disability claim, concomitant treatment with other analgesics or psychotropic drugs	Number approached and eligible not reported 205 enrolled (103 sustained release, 102 immediate release)
Wiesel, 1980 Acute low back pain: an objective analysis of conservative therapy.	To analyze roles of bed rest, anti-inflammatory and analgesic medication in treatment of lumbago, measuring effect on pain relief and return to full daily activity.	RCT	No previous back problem. Results of neurologic examination, straight leg raising test and lumbosacral spine roentgenograms within normal limits.	Not reported	Not reported Not reported 75 enrolled in analgesic medication trial

Appendix E6. Trials of Opioids and Tramadol Included in the APS/ACP Review

Author, Year, Title	Subject Age, Gender, Diagnosis	Country and Setting	Sponsor	Measures
Salzman, 1998 Can a controlled release oral dose form of oxycodone be used as readily as an immediate release form for the purpose of titrating to stable pain control?	Avg. 56 years 54% Female 87% White 13% Hispanic Intervertebral disc disease, nerve root entrapment, spondylolisthesis, osteoarthritis, and other nonmalignant conditions 84% (48/57) Pain duration not reported	US Multicenter (5) Rheumatology clinics and others	Purdue Pharma sponsored study. 2 authors employees of Purdue. Role not otherwise reported.	**Pain Intensity**: daily diary, categorical scale (0-3, none-severe) **Study Medication Use**: daily diary, amount used **Rescue Drug Use**: daily diary, amount used **Achievement of Stable Pain Control**: Stable pain control considered achieved if pain intensity rated as 1.5 or less for 48 hours with no more than 2 doses of rescue medication **Time to Stable Pain Control**: Days
Sorge, 1997 Comparison of the analgesic efficacy and tolerability of tramadol 100 mg sustained-release tablets and tramadol 50 mg capsules for the treatment of chronic low back pain	Female gender: 52% vs. 59% Mean age: 51 vs. 49 years nonwhite race: Not reported Mean duration of pain: 9 years in both groups Baseline severity or underlying conditions: Not reported	Germany Multicenter Pain clinic	Grunenthal GmbH	Pain intensity: 4-point verbal rating scale (1=none to 4=severe) Pain relief: 5-point verbal rating scale (none to complete) Adverse events: self-reported or elicited using nonleading questions
Wiesel, 1980 Acute low back pain: an objective analysis of conservative therapy.	Mean age: 23 years Female gender: none Race: not reported Duration of pain and baseline pain intensity not reported Diagnosis: acute back strain - nonradiating LBP	US army hospital and outpatient clinic. Subjects were combat trainees.	Not reported	Average days to return to work

Appendix E6. Trials of Opioids and Tramadol Included in the APS/ACP Review

Author, Year, Title	Type of Intervention	Results	Duration of Followup
Salzman, 1998 Can a controlled release oral dose form of oxycodone be used as readily as an immediate release form for the purpose of titrating to stable pain control?	A: Long acting Oxycodone (titrated) B: Short acting Oxycodone (titrated) Titration comparison Mean dose A: 104 mg/day Mean dose B: 113 mg/day 10 days	Long acting Oxycodone (A) vs. short acting Oxycodone (B) **Pain Intensity**: Not significantly different at baseline. **Mean decrease in pain intensity**: 1.1 units (A) vs. 1.3 units (B) (NS) **Achievement of stable analgesia**: 87% (26) (A) vs. 96% (26) (B) (p = 0.36) 5/47 patients did not achieve stable analgesia: 1 titrated to maximum dose of short acting without control (80 mg); 4 experienced adverse side effects (3 long acting, 1 short acting) **Time to stable pain control**: 2.7 days (A) vs. 3.0 days (B) (p = 0.90). **Mean number of dose adjustments**: 1.1 adjustments (A) vs. 1.7 adjustments (B) (p = 0.58)	10 days
Sorge, 1997 Comparison of the analgesic efficacy and tolerability of tramadol 100 mg sustained-release tablets and tramadol 50 mg capsules for the treatment of chronic low back pain	A: Tramadol sustained release 100 mg twice a day B: Tramadol immediate release 50 mg four times a day 3 weeks intervention Additional tramadol sustained release 100 mg twice daily allowed if pain uncontrolled after 1 week	Tramadol sustained-release versus tramadol immediate-release Pain relief 'complete', 'good', or 'satisfactory': 88% (52/59) vs. 86% (49/57; results only reported for persons who completed three-week course Pain relief 'complete': 8.5% (5/59) vs. 5.3% (3/57); results only reported for persons who completed three-week course	3 weeks
Wiesel, 1980 Acute low back pain: an objective analysis of conservative therapy.	A: Codeine 60 mg QID B: Oxycodone + aspirin 1 tablet QID (doses not specified) C: Acetaminophen 1 tablet bid (doses not specified) 14 days	Codeine (A) vs. oxycodone + aspirin (B) vs. acetaminophen (C) Mean number of days before return to work: 10.67 vs. 12.0 vs. 13.0 (NS)	15 days of treatment

Appendix E6. Trials of Opioids and Tramadol Included in the APS/ACP Review

Author, Year, Title	Loss to Followup	Compliance to Treatment	Adverse Events and Withdrawals Due To Adverse Events	Quality Rating	Comments
Salzman, 1998 Can a controlled release oral dose form of oxycodone be used as readily as an immediate release form for the purpose of titrating to stable pain control?	10 (18%) 57 analyzed	Not reported	Long-acting oxycodone vs. short-acting oxycodone Somnolence: 8/30 (27%) vs. 10/27 (37%) Nausea: 15/30 (50%) vs. 9/27 (33%) Vomiting: 6/30 (20%) vs. 1/27 (4%) Postural hypotension: 0% vs. 0% Constipation: 9/30 (30%) vs. 10/27 (37%) Pruritus: 9/30 (30%) vs. 7/27 (26%) Confusion: 1/30 (3%) vs. 0% Dry mouth: 0/30 (0%) vs. 3/27 (11%) Dizziness: 9/30 (30%) vs. 6/27 (22%) Nervousness: 0/30 (0%) vs. 2/27 (7%) Asthenia: 2/30 (7%) vs. 3/27 (11%) Headache: 4/30 (13%) vs. 7/27 (26%) Withdrawal due to adverse events: 6/30 (20%) vs. 2/27 (7%)		Incomplete and confusing report of results. No standardized measures of pain.
Sorge, 1997 Comparison of the analgesic efficacy and tolerability of tramadol 100 mg sustained-release tablets and tramadol 50 mg capsules for the treatment of chronic low back pain	9 excluded due to 'protocol violations', another 80 did not complete 3-week course	Not reported	Tramadol sustained-release vs. tramadol immediate-release Any adverse event: 54% (56/103) vs. 53% (54/102) Withdrawal due to adverse event: 15% (15/103) vs. 19% (19/102) Headache: 4% vs. 8% (approximate, based on graph) Rates of nausea, dizziness, vomiting, constipation, tiredness, constipation, diaphoresis, dry mouth similar between groups		
Wiesel, 1980 Acute low back pain: an objective analysis of conservative therapy.	Not reported	Not reported	Not reported		

Please see Appendix C. Included Studies for full study references.

Appendix E7. Data Abstraction of Systematic Reviews of Opioids

Author, Year	Comparison	Data Sources	Number and Type of Studies	Interventions and Number of Patients	Methods for Rating Methodological Quality of Primary Studies	Methods for Synthesizing Results of Primary Studies
Chaparro, 2014	1. Strong opioids vs. placebo 2. Tramadol vs. placebo 3. Buprenorphine vs. placebo 4. Tramadol vs. celecoxib 5. Opioids vs. antidepressants	No language restriction MEDLINE, EMBASE, Cochrane Library, PsycINFO, CINAHL, all through Oct. 2012 Citation tracking of identified trials	≥ 50% of participants had chronic LBP, defined as ≥12 weeks Adults with or without leg pain Excluded intravenous or neuraxial administration; other routes included RCTs with blinded outcome assessment Outpatient treatment, opioid Rx ≥ 1 month Must have reported on pain, function, or global improvement	1. Strong opioids: 1154; Placebo: 733 2. Tramadol: 689; Placebo: 689 3. Buprenorphine: 312; Placebo: 341 4. Tramadol: 785; Celecoxib: 798 5. Opioids: 135; Antidepressants: 137	GRADE approach	Data pooled in meta-analysis, performed with both fixed-effect and random-effect models; more conservative result reported

Appendix E7. Data Abstraction of Systematic Reviews of Opioids

Author, Year	Results	Adverse Events	Number of Trials For Meta-analysis	Heterogeneity	Quality
Chaparro, 2014	1. Pain: moderate quality evidence that strong opioids are better than placebo; SMD 0.43 lower (95% CI 0.52 to 0.33); Function: Moderate quality evidence better than placebo in improving function (SMD 0.26 lower disability score (95% CI 0.37 to 0.15) 2. Pain: low quality evidence tramadol is better than placebo, SMD 0.55 lower, 95% CI 0.66 to 0.44 ; Function: Moderate evidence tramadol is better than placebo, SMD 0.18 lower (95% CI 0.29 to 0.07) 3. Pain: very low quality evidence that transdermal buprenorphine is better than placebo (MD 0.58 lower, 95%CI 0.61 to0.55; Function: very low quality evidence of no difference in function (MD 3 lower (95% CI 11.44 lower to 5.44 higher) 4. Pain: very low quality evidence that tramadol is better than celecoxib; RAD note: this seems to be a misprint; in fact, celecoxib appeared to be better than tramadol (at least 30% pain reduction: 63.7% with celecoxib; 52.5% with tramadol, OR 0.63 (95% CI 0.52, 0.77) 5. Pain: very low quality evidence that opioids and antidepressants do not differ (SMD 0.21, 95%CI -0.03 to 0.45); Function: very low quality evidence that that opioids and antidepressants do not differ (SMD -0.11, 95% CI -0.63 to 0.42)	For strong opioids: Somnolence: 2.5% placebo; 8.6% opioids Nausea: 10.2% placebo; 22.3% opioids; Constipation: 3.6% placebo; 14.8% opioids, all statistically significant	1. 7 RCTs 2. 5 RCTs 3. 2 RCTs for pain; one for function 4. Only 1 RCT, no meta-analysis 5. 2 RCTs	1. I^2 = 0% for both pain and function 2. I^2 = 86% for pain, 0% for function 3. I^2 =99% for pain 4. Only 1 trial 5. I^2 for pain, 0%; only 1 trial for function	Good

Please see Appendix C. Included Studies for full study references.

Appendix E8. Data Abstraction of Randomized Controlled Trials of Opioids

Author, Year	Country Number of Centers and Setting	Inclusion Criteria	Number Randomized, Analyzed Attrition	Intervention	Study Participants	Duration of Pain (acute, subacute, chronic)	Outcome Measures
Cloutier 2013	probably Canada, but not certain; 10 centers; setting unclear	Age>18 Back pain intensity ≥2 on a 0-4 scale (moderate or severe) Currently taking opioids Low back pain ≥3 mos. Must undergo 2-7 day washout of pre-study opioids Exclusions: psychological dependence on opioids or alcohol; major psychiatric disorder; litigation	Randomized: 83 Analyzed: 54 for per-protocol analysis (completed at least 2 weeks each of active therapy and placebo) Attrition: 29 (35%) The intention-to-treat analysis included all 83, who had at least one dose of medication and at least one post-randomization data point.	A. Oxycodone/ Naloxone, both controlled release, titrated dose of 10mg/5mg q 12h up to 40mg/20mg q 12 h B. placebo Crossover design: 4 weeks of each intervention	Due to crossover design, all patients received both A and B. Among the 54 analyzed: women=50% Mean age=50.6 Caucasian: 94.4% Baseline score on Pain and Disability Index was 42 on a 0-70 scale (70 worst) Among the full 83 enrolled, 39 men, 44 women; mean age 51.3; 91.6% Caucasian	Subacute or chronic	Pain ordinal scale, 0-4 (0=none, 4=excruciating); Pain VAS - 100mm; Pain & Sleep Questionnaire: each item on a 0-100 VAS; Pain Disability Index: overall score 0-70, with 70 worst; Quebec Back Pain Disability Questionnaire: 20 items on 0-5 ordinal scale; Bowel Function Index: 3 items on numerical analog scale, 0-100; General Health status scale from SF-36; Effectiveness of Treatment on 4-point scale; Global Impression of change on 7-point scale

Appendix E8. Data Abstraction of Randomized Controlled Trials of Opioids

Author, Year	Duration of Followup	Results	Adverse Events Including Withdrawals	Funding Source	Quality Rating	Comments
Cloutier 2013	4 weeks each on active therapy and placebo	Intention-to-Treat Analysis (n=83): Pain VAS: A. 52.2 mm (SD 23.0; B: 57.8 mm (SD 24.2) (p=0.053) Ordinal pain score: A: 2.3 (SD 0.8); B: 2.5 (SD 0.9), (p=0.086) No other results for ITT analysis Per protocol analysis: Pain VAS: A. 48.6 mm (SD 23.1); B: 55.9 mm (SD 25.4) (p=0.03) Ordinal pain score: A: 2.1 (SD 0.8); B: 2.4 (SD 0.9), (p=0.042) Pain Disability Index: A: 34.3 (SD 15.6); B:37.5 (SD 15.2), p=0.051; SF-36 General Health: "no difference" Quebec Back Pain Disability: "no difference"	Withdrawals: 9 dropouts during active treatment; 11 during placebo treatment; Withdrawals due to AE's: 6 on active therapy, 5 on placebo Bowel Function Index and use of rescue laxatives: no significant differences Overall count of AE's: A. 48, B: 40, p=0.068 Serious AE's: 2 in each group; all judged not related to study meds. Somnolence: A: 5.4%; B: 0.0%, p=0.046 Other AE's (nausea, constipation, fatigue, vomiting, dizziness, abdominal pain): no significant differences	Purdue Pharma		Main intent of oral naloxone was to reduce constipation side effects; there is very low systemic bioavailability due to first-pass metabolism by liver.

Appendix E8. Data Abstraction of Randomized Controlled Trials of Opioids

Author, Year	Country Number of Centers and Setting	Inclusion Criteria	Number Randomized, Analyzed Attrition	Intervention	Study Participants	Duration of Pain (acute, subacute, chronic)	Outcome Measures
Hale, 2005	US Multicenter Number and type of clinic setting not described	18 to 75 years, moderate to severe low back pain for at least 15 days per month for past 2 months, stable dose of opioids for at least 3 days prior to enrollment	420 screened 330 underwent randomized titration 235 enrolled in stable dose intervention phase	A: Long acting oxymorphone (titrated) (Mean dose 79.4 mg/day) B: Long acting oxycodone (titrated) (Mean dose 155 mg/day) C: Placebo 18 days	Median age=46 years 47% female Race not reported Median duration of low back pain 8 years "Most common" etiologies: degenerative disc disease, disc herniation, fracture, spondylosis, and spinal stenosis		Pain intensity on VAS (0 to 100) at baseline and at 18 days and by 4 point categorical scale (0=none to 3=severe) Pain relief on VAS (0=no relief to 100=complete relief) Brief pain inventory Global evaluation on 5-point categorical scale (poor to excellent) Interference with normal activities on 100 point scale (0=no interference to 10=complete interference)

Appendix E8. Data Abstraction of Randomized Controlled Trials of Opioids

Author, Year	Duration of Followup	Results	Adverse Events Including Withdrawals	Funding Source	Quality Rating	Comments
Hale, 2005	18 days	Long-acting oxymorphone (n=71) (A) vs. long-acting oxycodone (n=75) (B) vs. placebo (n=67) (C) Pain Intensity (100 point VAS) Compared to C differences were -18.21 and -18.55 for A and B (p=0.0001 for each comparison) Pain Intensity Categorical scale: Proportion rating pain intensity "none" or "mild" similar for A and B (around 14%) vs. C (45%) Pain Relief 56.8 vs. 54.1 vs. 39.1 Pain Interference A and B similar and superior to C for general activity, mood, normal work, relations with other people, and enjoyment of life (no difference for sleep and walking ability) Global Assessment "Good", "very good", or "excellent': 59% vs. 63% vs. 27% Discontinuation due to treatment failure (treatment phase) 20% vs. 16% vs. 57% Discontinuation due to treatment failure (dose titration phase) 7/166 (4.2%) vs. 4/164 (2.4%) Rescue medication use 13.8 vs. 14.7 mg/day after first 4 days	Long-acting oxymorphone (A) vs. long-acting oxycodone (B) vs. placebo (C) Constipation: 39/110 (35%) vs. 32/111 (29%) vs. 12/108 (11%) Sedation: 19/110 (17%) vs. 22/111 (20%) vs. 2/108 (2%) Any adverse events: 85% vs. 86% vs. NR "Serious" adverse events possibly or probably related to study medication: 2 vs. 1 vs. NR (sample sizes not clear) Withdrawal (overall, titration phase): 53/166 (32%) vs. 42/164 (26%) Withdrawal (overall, treatment phase): 22/80 (28%) vs. 21/80 (26%) vs. 53/75 (71%) Withdrawal (adverse events, titration phase): 25/166 (15%) vs. 26/164 (16%) Withdrawal (adverse events, treatment phase): 2/80 (2.5%) vs. 4/80 (5.0%) vs. 5/75 (6.7%)	Endo Pharmaceuticals Inc and Penwest Pharmaceuticals Co		High number of patients screened and enrolled in titration phase not enrolled into randomized phase

Appendix E8. Data Abstraction of Randomized Controlled Trials of Opioids

Author, Year	Country Number of Centers and Setting	Inclusion Criteria	Number Randomized, Analyzed Attrition	Intervention	Study Participants	Duration of Pain (acute, subacute, chronic)	Outcome Measures
Hyup Lee 2013	15 centers South Korea	Age 25-75 years, able to walk, with moderate to severe LBP with average intensity ≥4 and duration ≥3 months requiring analgesics Exclude: recent back surgery or steroid injection, more severe pain in an area other than the back, or comorbid conditions that may interfere with assessment	248 randomized 196 completed (21% attrition)	A. Extended-release tramadol HCl 75 mg/acetaminophen 650 mg fixed-combination tablet (n=125) Max dose=4 tabs/d=300 mg tramadol B. Placebo (n=120)	A vs. B Mean age: 59.9 vs. 60.4 years Female sex: 75% vs. 74% Race: NR	Subacute or chronic	10-cm VAS, SF-36, ODI

Appendix E8. Data Abstraction of Randomized Controlled Trials of Opioids

Author, Year	Duration of Followup	Results	Adverse Events Including Withdrawals	Funding Source	Quality Rating	Comments
Hyup Lee 2013	29 days	A vs. B Pain intensity change ≥30%, full analysis set: 57.7% (49/85) vs. 41.1% (37/90); p=0.037 Pain intensity change ≥30%, per protocol: 63% (46/73) vs. 44.9% (35/78); p=0.027 Pain intensity change ≥50%, full analysis set: 31.8% vs. 20.0%; p=0.075 Pain intensity change ≥50%, per protocol: 34.3% vs. 21.8%; p=0.088 Korean SF-36: patients in the intervention group had significant improvements in role-physical, general health, and reported health transition domains, and a tendency (p=0.052) toward improvement in vitality Korean ODI: patients in the intervention group had significant functional improvement in the personal care section (p=0.045) and a tendency (p=0.053) toward improvement in total ODI scores	A vs. B Any adverse event: 83.2% (104/125) vs. 54.2% (65/120); RR 1.54 (95% CI 1.28 to 1.84) Withdrawal due to adverse event: 19.2% (24/125) vs. 5.0% (6/120); RR 3.31 (95% CI 1.40 to 7.83)	Janssen Korea, Ltd.	Good	Also available: patient-reported efficacy, investigator-reported pain improvement, all subscores of SF-36 (Table 2) and ODI (Table 3), specific AEs

Appendix E8. Data Abstraction of Randomized Controlled Trials of Opioids

Author, Year	Country Number of Centers and Setting	Inclusion Criteria	Number Randomized, Analyzed Attrition	Intervention	Study Participants	Duration of Pain (acute, subacute, chronic)	Outcome Measures
Jamison, 1998	Randomized trial US Single center Pain clinic	Chronic back pain >6 months duration, age 25 to 65 years, average pain intensify >40 on scale of 0 to 100, unsuccessful response to traditional pain treatment	48 screened Not reported 36 enrolled Attrition: none in randomized phase	A: Long acting morphine + short-acting oxycodone (titrated doses) + Naproxen B: Short-acting oxycodone (set dose) + Naproxen C: Naproxen Mean dose A: 41.1 mg morphine equivalent/day Mean dose B: Not reported, max 20 mg oxycodone/day Mean dose C: Not reported In all groups, max 1000 mg/day of naproxen 16 weeks	Avg. 43 years 57% female Race not reported 39% failed back syndrome 25% myofascial pain syndrome 19% degenerative spine disease 14% radiculopathy 3% discogenic back pain Prior opioid use not reported Average pain duration 79 months		Pain Intensity: timing not specified, Comprehensive Pain Evaluation Questionnaire Functional status: baseline and at end of treatment (SF-36) Symptom checklist: baseline and at end of treatment (Symptom Checklist-90) Weekly activity record at baseline and once a month Medication diary weekly Overall helpfulness during titration and at end of study (categorical scale, 0= no help, 10=extremely helpful)

Appendix E8. Data Abstraction of Randomized Controlled Trials of Opioids

Author, Year	Duration of Followup	Results	Adverse Events Including Withdrawals	Funding Source	Quality Rating	Comments
Jamison, 1998	16 weeks	Long acting Morphine + short acting Oxycodone + naproxen (A) vs. short acting Oxycodone + naproxen (B) vs. naproxen (C) Average pain (means, 0-100 VAS): 54.9 vs. 59.8 vs. 65.5 Current pain (means, 0-100 VAS): 51.3 vs. 55.3 vs. 62.7 Highest pain (means, 0-100 VAS): 71.4 vs. 75.5 vs. 78.9 Anxiety (means): 11.2 vs. 15.0 vs. 31.6 Depression (means): 10.8 vs. 16.4 vs. 26.9 Irritability (means): 17.7 vs. 20.5 vs. 33.7 Level of activity (means, 0-100 scale): 49.3 vs. 49.3 vs. 51.5 Hours of sleep (means): 5.9 vs. 5.9 vs. 6.1	Long-acting morphine + short-acting oxycodone + naproxen vs. short-acting oxycodone + naproxen vs. naproxen (proportion reported weekly, sample sizes not clear) Dry mouth: 35% vs. 26% vs. 19% Drowsiness: 37% vs. 22% vs. 15% Headache: 32% vs. 20% vs. 15% Constipation: 30% vs. 18% vs. 10% Nausea: 31% vs. 14% vs. 5% Itching: 15% vs. 15% vs. 9% Dizziness: 6% vs. 19% vs. 9% Muddled thinking: 0% vs. 1.4% vs. 3% Withdrawal due to adverse events: 1/11 (9.1%) vs. 2/13 (15%) vs. 0/12 (0%)	Roxane Laboratories sponsored study (maker of long-acting morphine and short-acting oxycodone). Not clear if authors employed by Roxane.		Nonequivalent dose of opioids given. Only long-acting morphine group had dose titrated for pain. Most statistical comparisons involved comparisons across all three groups (including naproxen only arm). No blinding

Appendix E8. Data Abstraction of Randomized Controlled Trials of Opioids

Author, Year	Country Number of Centers and Setting	Inclusion Criteria	Number Randomized, Analyzed Attrition	Intervention	Study Participants	Duration of Pain (acute, subacute, chronic)	Outcome Measures
Rauck 2014	59 centers United States	Males and non-pregnant, non-lactating females age 18-75 years, with moderate-to-severe chronic LBP for ≥3 months, average pain score ≥4 Exclude: history of opioid or alcohol or illicit drug abuse in previous 5 years, history of intolerance to hydrocodone or acetaminophen N-acetyl-para-aminophenol, comorbid conditions that could interfere with pain assessment, uncontrolled blood pressure, BMI >45, or depression	302 randomized 183 completed (39% attrition)	A. Extended-release hydrocodone in 10-, 20-, 30-, 40-, and 50-mg capsules (n=151) Mean dose=119 mg/d Max dose=200 mg/d B. Placebo (n=151)	A vs. B Mean age: 50.4 vs. 50.8 years Female sex: 62% vs. 49%; p=0.028 Race: 82% White, 17% Black, 1% other vs. 80% White, 17% Black, 4% other Mean pre-study opioid usage: 76.8 vs. 79.2 mg/day MED Mean pain score before titration (NRS): 6.9 vs. 6.9 Mean pain score after titration (NRS): 3.1 vs. 3.1	Chronic	10-point NRS

Appendix E8. Data Abstraction of Randomized Controlled Trials of Opioids

Author, Year	Duration of Followup	Results	Adverse Events Including Withdrawals	Funding Source	Quality Rating	Comments
Rauck 2014	12 weeks	A vs. B Change from baseline in mean daily pain intensity score: 0.48 vs. 0.96; p=0.008	A vs. B Withdrawal due to adverse event: 1.3% (2/151) vs. 3.3% (5/151); RR 0.40 (95% CI 0.08 to 2.03)	Zogenix, Inc.	Poor	Dosages, specific AEs EERW design

Appendix E8. Data Abstraction of Randomized Controlled Trials of Opioids

Author, Year	Country Number of Centers and Setting	Inclusion Criteria	Number Randomized, Analyzed Attrition	Intervention	Study Participants	Duration of Pain (acute, subacute, chronic)	Outcome Measures
Schiphorst Preuper 2014	2 centers The Netherlands	Age ≥18 years, with chronic LBP lasting >3 months, a VAS score ≥4 Exclude: hypertension, mental or physical conditions leading to reduced functioning	50 randomized 43 completed (14% attrition)	A. tramadol 37.5 mg/acetaminophen 325 mg fixed-combination capsule (n=25) Max dose tramadol=225 mg/d B. Placebo (n=25)	A vs. B Mean age: 42 vs. 44 years Female sex: 72% vs. 64% Race: NR Mean duration of pain: 18 vs. 24 months Mean pain score (VAS): 6.1 vs. 4.7	Chronic	Lifting, carrying, and bending; 10-cm VAS; RMDQ; global pain assessment
Wiesel, 1980	US army hospital and outpatient clinic. Subjects were combat trainees.	No previous back problem. Results of neurologic examination, straight leg raising test and lumbosacral spine roentgenograms within normal limits.	Not reported Not reported 75 enrolled in analgesic medication trial	A: Codeine 60 mg QID B: Oxycodone + aspirin 1 tablet QID (doses not specified) C: Acetaminophen 1 tablet bid (doses not specified) 14 days	Mean age: 23 years Female gender: none Race: not reported Duration of pain and baseline pain intensity not reported Diagnosis: acute back strain - nonradiating LBP		Average days to return to work

Appendix E8. Data Abstraction of Randomized Controlled Trials of Opioids

Author, Year	Duration of Followup	Results	Adverse Events Including Withdrawals	Funding Source	Quality Rating	Comments
Schiphorst Preuper 2014	2 weeks	A vs. B Lifting (kg), baseline-followup: 18-19 vs. 20-17 kg; change 1 vs. -3 kg Carrying (kg), baseline-followup: 24-20 vs. 24-21 kg; change -4 vs. -3 Static bending (s), baseline-followup: 119-143 vs. 158-192.5; change 24 vs. 34.5 s Dynamic bending (s/rep), baseline-followup: 2.7-2.8 vs. 2.7-3.0; change 0.1 vs. 0.3 Roland Morris Disability Questionnaire (0-24), baseline-followup: 13.0-11.5 vs. 13.0-13.0; change -1.5 vs. 0 VAS current pain, baseline-followup: 6.1-5.1 vs. 4.7-4.5; change -1 vs. -0.2 VAS, maximum pain, baseline-followup: 7.3-7.4 vs. 7.1-7.7; change 0.1 vs. 0.6 VAS, minimum pain, baseline-followup: 4.4-3.8 vs. 2.0-2.6; change -0.6 vs. 0.6 Pain relief: 42% (10/24) vs. 4% (1/25); RR 10.42 (95% CI 1.44 to 75.29) Same pain or worsened: 58% (14/24) vs. 96% (24/25); RR 0.61 (95% CI 0.43 to 0.86)	A vs. B Withdrawal due to adverse event: 8% (2/25) vs. 0% (0/25)	Grunenthal BV and Stichting Beatrixoord	Fair	
Wiesel, 1980	15 days of treatment	Codeine (A) vs. oxycodone + aspirin (B) vs. acetaminophen (C) Mean number of days before return to work: 10.67 vs. 12.0 vs. 13.0 (NS)	Not reported	Not reported		Incomplete and confusing report of results. No standardized measures of pain.

Please see Appendix C. Included Studies for full study references.

Appendix E9. Trials of Skeletal Muscle Relaxants Included in the APS/ACP Review

Author, Year, Title	Purpose of Study	Study Design	Inclusion Criteria	Exclusion Criteria	Number of Treatment and Control Subjects (number approached, number eligible, number enrolled)
Borenstein, 2003 Efficacy of a low-dose regimen or cyclobenzaprine hydrochloride in acute skeletal muscle spasm: results of two placebo controlled trials	To evaluate the efficacy and safety of cyclobenzaprine 5 mg tid relative to 10 mg tid and placebo	RCT	Outpatients >18 years with acute (<14 days), moderate or moderately severe painful muscle spasm of the lumbar and/or cervical region	Inability to discontinue other meds for low back pain prior to study, vertebral body of spinous process percussive tenderness, unexplained constipation, diarrhea, or urinary retention, contraindications to use of cyclobenzaprine, psychiatric or drug abuse diagnoses, related worker's compensation issue, pregnant or breast feeding, elevated blood pressure, recent myocardial infarction	Number approached and eligible not reported 737 enrolled (242 cyclobenzaprine 5 mg tid, 249 cyclobenzaprine 10 mg tid, 246 placebo)

Appendix E9. Trials of Skeletal Muscle Relaxants Included in the APS/ACP Review

Author, Year, Title	Subject Age, Gender, Diagnosis	Country and Setting	Sponsor	Measures
Borenstein, 2003 Efficacy of a low-dose regimen or cyclobenzaprine hydrochloride in acute skeletal muscle spasm: results of two placebo controlled trials	Cyclobenzaprine 5 mg po tid vs. 10 mg po tid vs. placebo Mean age (years): 42 vs. 42 vs. 42 Female gender: 57% vs. 57% vs. 59% Race (nonwhite): 14% vs. 12% vs. 14% Baseline severity and duration: Not reported Lumbar pain: 66% vs. 65% vs. 63% Prior muscle relaxant use: Not reported	U.S. Multicenter	Merck & Co., Inc	Patient rated global change: 0 (worsening) to 4 (marked improvement) scale Patient rated medication helpfulness: 0 (poor) to 4 (excellent) scale Patient rated relief from starting backache: 0 (no relief) to 4 (complete relief) scale Physician rating of muscle spasm: 0 (no hardness) to 4 (severe, boardlike hardness)

Appendix E9. Trials of Skeletal Muscle Relaxants Included in the APS/ACP Review

Author, Year, Title	Type of Intervention	Results
Borenstein, 2003 Efficacy of a low-dose regimen or cyclobenzaprine hydrochloride in acute skeletal muscle spasm: results of two placebo controlled trials	A: Cyclobenzaprine 5 mg po tid B: Cyclobenzaprine 10 mg po tid C: Placebo 7 days	Cyclobenzaprine 5 mg tid vs. 10 mg tid vs. placebo (results at end of treatment, 7 days) Global change: 2.88 vs. 2.82 vs. 2.47 (both active treatments p<0.001 compared to placebo) Medication helpfulness: 2.09 vs. 2.13 vs. 1.65 (both active treatments p<0.01 compared to placebo) Relief from starting backache: 2.37 vs. 2.38 vs. 2.00 (both active treatments p<0.03 vs. placebo) Withdrawals due to ineffectiveness: 2% (5/242) vs. 2% (5/249) vs. 4% (9/246)

Appendix E9. Trials of Skeletal Muscle Relaxants Included in the APS/ACP Review

Author, Year, Title	Duration of Followup	Loss to Followup	Compliance to Treatment	Adverse Events and Withdrawals Due To Adverse Events	Quality Rating	Comments
Borenstein, 2003 Efficacy of a low-dose regimen or cyclobenzaprine hydrochloride in acute skeletal muscle spasm: results of two placebo controlled trials	7 days			Cyclobenzaprine 2.5 mg tid vs. 5 mg tid vs. placebo (pooled with results of another trial conducted by same authors) Somnolence: 20% vs. 29% vs. 10% Dry mouth: 14% vs. 21% vs. 7% Headache: 7% vs. 5% vs. 8% Asthenia/fatigue: 4% vs. 6% vs. 3% Nausea: 4% vs. 3% vs. 4% Dizziness: 3% vs. 3% vs. 2% >1 adverse event: 44% vs. 55% vs. 35% Cyclobenzaprine 2.5 mg tid vs. 5 mg tid vs. placebo (nonpooled) Withdrawals: 9% (20/223) vs. 7% (15/222) vs. 9% (21/223) Withdrawals due to adverse events: 2% (5/223) vs. 4% (9/222) vs. 2% (4/223)		

Please see Appendix C. Included Studies for full study references.

Appendix E10. Data Abstraction of Randomized Controlled Trials of Skeletal Muscle Relaxants

Author, Year	Country Number of Centers and Setting	Inclusion Criteria	Number Randomized, Analyzed Attrition	Intervention	Study Participants	Duration of Pain (acute, subacute, chronic)	Duration of Followup
Pareek 2009	India Multicenter	Age 18-70 with acute low back pain and VAS score ≥6 at baseline (scale 0-10) Excluded: sciatica or other underlying spinal disorder, malignancy, osteoporosis	Randomized: 197 Analyzed: 185 Attrition: 6% (12/197)	A. Tizanidine 2 mg + aceclofenac 100 mg bid for 7 days (n=101) B. Aceclofenac 100 mg bid for 7 days (n=96)	A vs. B Mean age 62 vs. 58 years 39% vs. 40% female Race not reported Baseline pain, function not reported	Acute/subacute; mean duration not reported but inclusion criteria required <30 days pain	7 days
Ralph 2008	United States Multicenter	Age 18-65 years with moderate to severe acute low back pain ≤3 days Excluded: duration >3 days, sciatica, history of spinal pathology, neurologic symptoms, chronic low back pain, osteoporosis	Randomized: 562 Analyzed: 547 for efficacy, 561 for safety Attrition: efficacy 3% (15/547); safety 0.2% (1/561)	A. Carisoprodol 250 mg QID for 7 days (n=277) B. Placebo QID for 7 days (n=285	A vs. B Mean age 39 vs. 42 years 49% vs. 55% female Race: 74% vs. 77% Caucasian; 15% vs. 12% African; 10% vs. 10% Asian; 0.7% vs. 0.4% Native American; 0.4% vs. 0.4% other Baseline pain severity: mild 0.4% vs. 0.4%; moderate 74% vs. 74%; severe 25% vs. 26% Baseline RMDQ 10 vs. 10	Acute; mean duration 2 vs. 2 days	7 days

Appendix E10. Data Abstraction of Randomized Controlled Trials of Skeletal Muscle Relaxants

Author, Year	Results	Adverse Events Including Withdrawals	Funding Source	Quality Rating
Pareek 2009	A vs. B Pain at rest, mean change from baseline day 3: -3.01 vs. -1.90, p=0.0001; day 7 -5.88 vs. -4.35, p=0.0001 Pain with movement, mean change from baseline day 3: -2.94 vs. -1.81, p=0.0001; day 7 -6.09 vs. -3.98, p=0.0001 Global improvement, proportion of patients reporting good or excellent response: 75% (71/94) vs. 34% (31/94); RR 1.28 (95% CI 1.07 to 1.52)	A vs. B No serious adverse events in either group Vomiting: 5% (5/101) vs. 7% (7/96); RR 0.68 (95% CI 0.22 to 2.07) Dizziness: 5% (5/101) vs. 4% (4/96); RR 1.19 (95% CI 0.33 to 4.29)	Ipca Laboratories	Fair
Ralph 2008	A vs. B Pain, patient-rated impression of pain relief, mean change from baseline day 3 (scale 0-4; higher score = greater pain relief): 1.8 vs. 1.1, p<0.0001; day 7 between-group difference p<0.0001 (data not shown) Global improvement, patient-rated impression of change, mean change from baseline at day 3 (scale 0-4; higher score = greater improvement); 2.3 vs. 1.7, p<0.0001; day 7 between-group difference p<0.0001 (data not shown)	A vs. B No serious adverse events in either group Withdrawals due to adverse events: 3% (8/277) vs. 2% (5/284); RR 1.64 (95% CI 0.54 to 4.95) Drowsiness: 13% (37/277) vs. 5% (13/284); RR 2.92 (95% CI 1.59 to 5.37) Dizziness: 10% (27/277) vs. 3% (9/284); RR 3.08 (95% CI 1.47 to 6.42) Headache: 4% (10/277) vs. 1% (4/284); RR 2.56 (95% CI 0.81 to 8.08)	MedPointe Pharmaceuticals	Fair

Please see Appendix C. Included Studies for full study references.

Appendix E11. Data Abstraction of Randomized Controlled Trials of Benzodiazepines

Author, Year	Country Number of Centers and Setting	Inclusion Criteria	Number Randomized, Analyzed Attrition	Intervention	Study Participants	Duration of Pain (acute, subacute, chronic)
Studies published since the APS review						
Brotz, 2010	Germany Single center	18 to 75 years of age, sciatica with or without neurological deficit due to lumbar disc prolapse, CT or MRI confirmation of lumbar disc prolapse, pain centralization within the first physical therapy session Exclude: bladder or bowel disturbance, acute (<24 h) development of paresis grade 1 or plegia; benzodiazepine in last 2 weeks, benzodiazepine intolerance, prior disc prolapse surgery, prior trauma to the vertebral column	Randomized: 60 (30 vs. 30) Analyzed: 60 Attrition: Reports none	A: Diazepam: 5 mg po bid x 5 d, then tapered (tapering regimen not specified) (n=30) B: Placebo (n=30)	Mean age: 43 vs. 42 years Female: 37% vs. 50% Race: Not reported Baseline pain (median, 0-10 VAS): 8 vs. 8 Baseline RDQ (median, 0-24): 14 vs. 14	Duration not specified, 93% <90 days

Appendix E11. Data Abstraction of Randomized Controlled Trials of Benzodiazepines

Author, Year	Duration of Followup	Results	Adverse Events Including Withdrawals	Funding Source	Quality Rating
Studies published since the APS review					
Brotz, 2010	1 year (treatment 5 days)	A vs. B Duration of inability to work (median, days): 26 vs. 15 (p=0.73) RDQ (median improvement, 0-24): 3.0 vs. 5.0 at 1 w (p=0.67) RDQ (median, 0-24): 2 vs. 1 at 1 y Diclofenac consumption (median, mg): 750 vs. 750 at 1 w (p=0.78) Pain improved ≥50%: 41% (12/29) vs. 79% (23/29) at 1 w, RR 0.5 (95% CI 0.3 to 0.8); Sensory loss improved: 83% (15/18) vs. 86% (19/22) at 1 w, RR 1.0 (95% 0.7 to 1.3) Sensory loss: 43% (9/21) vs. 44% (10/23) at 1 y Reduction of paresis: 22% (6/27) vs. 28% (8/28) at 1 w, RR 0.8 (95% CI 0.3 to 2.0) Paresis: 14% (3/21) vs. 13% (3/23) at 1 y Inability to work beyond d 28: 55% (16/29) vs. 41% (12/29) at 1 w, RR 1.3 (95% CI 0.7 to 2.2) Request for additional analgesics: 51% (15/29) vs. 41% (12/29) at 1 w, RR 1.3 (95% CI 0.7 to 2.3) Underwent surgery: 7 vs. 6 at 6 w, 8 vs. 7 at 1 y	Not reported	University of Tubingen	Good

Please see Appendix C. Included Studies for full study references.

Appendix E12. Data Abstraction of Systematic Reviews of Antidepressants

Author, Year	Comparison	Databases Searched, Date of Last Search	Number and Type of Studies	Interventions and Number of Patients	Methods for Rating Methodological Quality of Primary Studies
Urquhart, 2010	Antidepressant vs. placebo	MEDLINE, EMBASE, PsycINFO and CCRCT through November 2008	10 RCTs; 9 trials conducted in pts with chronic low back pain; 1 trial duration of low back pain not reported. Duration of followup 10 days to 12 weeks.	A. Antidepressants (n=315): paroxetine (3 studies); desipramine (3 studies); imipramine (2 studies); maprotiline (2 studies); fluoxetine (2 studies); bupropion, trazodone, amitriptyline, nortriptyline and clomipramine IV (1 study each) B. Placebo (n=252)	Cochrane Back Review Group criteria (2003)

Appendix E12. Data Abstraction of Systematic Reviews of Antidepressants

Author, Year	Methods for Synthesizing Results of Primary Studies	Results	Adverse Events	Quality
Urquhart, 2010	Random effects model assessing standardized mean differences (SMD)	A vs B Pain (9 studies): SMD -0.04 (95% CI -0.25 to 0.17; I2=0%) -Pain, SSRIs (3 studies): SMD 0.11 (95% CI -0.17 to 0.39; I2=0%) -Pain, tricyclic antidepressants (4 studies): SMD -0.10 (95% CI -0.51 to 0.31; I2-32%) Depression (2 studies): SMD 0.06 (95% CI -0.29 to 0.40) Functional status (2 studies): SMD -0.06 (95% CI -0.40 to 0.29)	Not reported	Good

Please see Appendix C. Included Studies for full study references.

Appendix E13. Data Abstraction of Randomized Controlled Trials of Antidepressants

Author, Year	Country Number of Centers and Setting	Inclusion Criteria	Number Randomized, Analyzed Attrition	Intervention	Study Participants	Duration of Pain (acute, subacute, chronic)	Duration of Followup
Farajirad 2013	Iran Single-center	Outpatient neurosurgery clinic patients age 18 to 70 years with chronic low back pain	Randomized: 60 Analyzed: unclear Attrition: unclear	A. Amitriptyline 25 mg/day titrated to 150 mg/day (maximum) by week 2 (n=NR) B. Sustained-release bupropion 150 mg/day titrated to 300 mg/day by week 2 (n=NR)	A vs. B Mean age 37 vs. 34 years No other demographic or clinical characteristics reported	Chronic; mean duration not reported	8 weeks
Mazza 2010	Italy Number of centers not reported	Adults with low back pain (with or without sciatica) for ≤6 months Excluded: prior back surgery, regular use of antidepressants or diagnosis of depression	Randomized: 85 Analyzed: 80 Attrition: 6% (5/85)	A. Escitalopram 20 mg/day (n=41) B. Duloxetine 60 mg/day (n=44)	A vs.B Mean age 52 vs. 54 years 56% vs. 57% female Pain, mean VAS (scale 0-10) 6.3 vs. 6.4 Function, mean Clinical Global Impressions of Severity Scale (CGI-S) score (scale 0-10) 3.6 vs. 3.5	Chronic; mean duration A vs. B: 12.3 vs.13.4 years	13 weeks

Appendix E13. Data Abstraction of Randomized Controlled Trials of Antidepressants

Author, Year	Results (list results for acute, subacute and chronic separately)	Adverse Events Including Withdrawals	Funding Source	Quality	Comments
Farajirad 2013	A vs.B No data shown Pain: No significant difference between groups	A vs. B Any adverse event (no details provided): 43% vs. 30%; p=0.3	Not reported	Poor	
Mazza 2010	A vs.B Pain, VAS mean change from baseline: -2.3 vs. -2.45; p=0.74 Quality of life, mean change SF-36 subscales: no significant difference between groups for any subscale -Bodily pain: 1.94 vs. 1.99 -General health: 1.22 vs. 1.13 -Mental health: 0.99 vs. 0.87 -Physical function: 2.11 vs. 2.54 -Emotional role: 0.80 vs. 0.76 -Physical role: 0.54 vs. 0.58 -Social function: 0.06 vs. 0.05 -Vitality: 0.14 vs. 0.12 Global improvement, CGI-S mean change from baseline: -0.92 vs. -0.69; p=0.21	A vs.B No mortality and no serious adverse events in any group Nausea: 5% (2/39) vs. 7% (3/41); p=0.69 Dry mouth: 10% (4/39) vs. 10% (4/41); p=0.94 Headache: 3% (1/39) vs. 5% (2/41); p=0.59 Constipation: 3% (1/39) vs. 2% (1/41); p=0.97 Dizziness: 5% (2/39) vs. 2% (1/41); p=0.54 Decreased appetite: 3% (1/39) vs. 2% (1/41); p=0.97 Insomnia: 8% (3/39) vs. 7% (3/41); p=0.95	No external funding	Fair	

Appendix E13. Data Abstraction of Randomized Controlled Trials of Antidepressants

Author, Year	Country Number of Centers and Setting	Inclusion Criteria	Number Randomized, Analyzed Attrition	Intervention	Study Participants	Duration of Pain (acute, subacute, chronic)	Duration of Followup
Skljarevski 2009	United States Number of centers not reported	Adults with chronic low back pain (duration ≥6 months) with or without sciatica and mean pain scores ≥4 Excluded: radicular compression, spinal stenosis, spondylolisthesis grade 3-4, back surgery within 12 months of study, invasive treatment of low back pain within 1 month of study	Randomized: 404 Analyzed: 404 Attrition: 0%	A. Duloxetine 20 mg/day (n=59) B. Duloxetine 60 mg/day (n=116) C. Duloxetine 120 mg/day (n=112) D. Placebo (n=117)	A vs. B vs. C vs. D Mean age 53 vs. 53 vs. 55 vs. 54 years 61% vs. 58% vs. 58% vs. 55% female Race: 78% vs. 78% vs. 82% vs. 80% white; 22% vs. 22% vs. 18% vs. 20% other Pain, mean BPI 6.4 vs. 6.2 vs. 6.1 vs. 6.2 Global health assessment, mean CGI-S score 4.1 vs. 3.5 vs. 3.6 vs. 3.7	Chronic; mean duration A vs. B vs. C vs. D: 12.5 vs. 10.5 vs. 13.9 vs. 10.3 years	13 weeks

Appendix E13. Data Abstraction of Randomized Controlled Trials of Antidepressants

Author, Year	Results (list results for acute, subacute and chronic separately)	Adverse Events Including Withdrawals	Funding Source	Quality	Comments
Skljarevski 2009	A vs. B vs. C vs. D Pain, VAS mean change from baseline: -1.77 vs. -2.46 vs. -2.40 vs. -2.10; no significant differences between groups Pain, Brief Pain Inventory - Severity scale average pain mean change from baseline: -1.79 vs. -2.50 vs. -2.45 vs. -1.87; B vs. D: p<0.05 Function, Brief Pain Inventory - Interference scale, average interference mean change from baseline: -1.84 vs. -2.40 vs. -1.92 vs. -1.61; B vs.D: p<0.05 Quality of life, mean change SF-36 subscales: -Bodily pain: 1.51 vs .1.95 vs. 2.11 vs. 1.36; B vs. D, C vs. D: p<0.05 No significant difference between groups for other subscales (general health, mental health, physical functioning, emotional role, physical role, social functioning, vitality) Quality of life, EuroQoL (EQ) 5D U.S. Index score mean change from baseline: 0.04 vs. 0.07 vs. 0.08 vs. 0.05; no significant differences between groups Global improvement, CGI-S mean change from baseline: -0.53 vs. -0.94 vs. -1.06 vs. -0.53; B vs. D, C vs. D: p<0.05	A vs.B vs. C vs. D No mortality in any group Serious adverse events: 1.7% (1/59) vs. 0.8% (1/116) vs. 2.7% (3/112) vs. 2.6% (3/117); no significant differences between groups Withdrawals due to adverse events: 15% (9/59) vs. 15% (17/116) vs. 24% (27/112) vs. 9% (10/117); C vs. D p<0.05 ≥1 adverse events: 64.4% (38/59) vs. 67.2% (78/116) vs. 72.3% (81/112) vs. 59.0% (69/117); C vs. D: p=0.04 Nausea, insomnia, dry mouth, constipation, somnolence and fatigue all significantly more likely with duloxetine use vs. placebo (p<0.05)	Eli Lilly	Good	

Appendix E13. Data Abstraction of Randomized Controlled Trials of Antidepressants

Author, Year	Country Number of Centers and Setting	Inclusion Criteria	Number Randomized, Analyzed Attrition	Intervention	Study Participants	Duration of Pain (acute, subacute, chronic)	Duration of Followup
Skljarevski 2010 (ENL ref. #694)	Germany, Netherlands, Poland, Russia, Spain, United States Multicenter	Age ≥18 years with chronic low back pain duration ≥6 months and BPI ≥4 Excluded: radicular compression, spinal stenosis, spondylolisthesis grade 3-4, back surgery within 12 months of study, invasive treatment of low back pain within 1 month of study, previous participation in duloxetine study, major depressive disorder or other psychiatric disorder	Randomized: 401 Analyzed: 394 Attrition: 1.7% (7/401)	A. Duloxetine 60 mg/day (n=198) B. Placebo (n=203)	A vs.B Mean age 55 vs. 53 years 60% vs. 63% female Race: 96% vs. 95% white, 3% vs. 3% African, 2% vs. 3% other Pain, mean BPI 5.8 vs. 5.8 Function, mean RMDQ 9.6 vs. 9.3 Global health assessment, mean CGI-S 3.5 vs. 3.3	Chronic; mean duration A vs. B 8.3 vs. 8.7 years	12 weeks

Appendix E13. Data Abstraction of Randomized Controlled Trials of Antidepressants

Author, Year	Results (list results for acute, subacute and chronic separately)	Adverse Events Including Withdrawals	Funding Source	Quality	Comments
Skljarevski 2010 (ENL ref. #694)	A vs.B Pain, BPI - Severity scale average pain mean change from baseline: -2.25 vs. -1.65; p=0.002 Pain, BPI 24-hour Average Pain Score, proportion of patients with 30% improvement in score: 57% (111/195) vs. 49% (97/199); p=0.11; 50% improvement in score: 49% (95/195) vs. 35% (69/199); p=0.005 Function, Brief Pain Inventory - Interference scale, average interference mean change from baseline: -2.01 vs. -1.43; p≤0.001 Function, RMDQ mean change from baseline: -2.69 vs. -2.22; p=0.26 Quality of life, Profile of Mood states total mood disturbance mean change from baseline: -6.77 vs. -2.77; p≤0.001 Global improvement, CGI-S mean change from baseline: -0.95 vs. -0.79; p=0.08 Global improvement, Patients' Global Impressions score, mean change from baseline: 2.88 vs. 3.19; p=0.01	A vs.B No mortality in either group Serious adverse events: 3% (5/198) vs. 0% (0/203); p=0.25 Withdrawals due to adverse events: 15% (30/198) vs. 5% (11/203); p=0.002 Specific adverse events more likely to occur in duloxetine group: nausea (p<0.001), dry mouth (p=0.03), somnolence (p=0.34); no difference for headache, constipation, dizziness	Eli Lilly	Fair	

Appendix E13. Data Abstraction of Randomized Controlled Trials of Antidepressants

Author, Year	Country Number of Centers and Setting	Inclusion Criteria	Number Randomized, Analyzed Attrition	Intervention	Study Participants	Duration of Pain (acute, subacute, chronic)	Duration of Followup
Skljarevski 2010 (ENL ref. # 818)	Brazil, France, Germany, Mexico, The Netherlands Multicenter	Age ≥18 years with chronic low back pain duration ≥6 months and BPI ≥4 Excluded: radicular compression, spinal stenosis, spondylolisthesis grade 3-4, back surgery within 12 months of study, invasive treatment of low back pain within 1 month of study, previous participation in duloxetine study, major depressive disorder or other psychiatric disorder	Randomized: 236 Analyzed: 225 Attrition: 5% (11/236)	A. Duloxetine 60 mg/day; titrated to 120 mg/day in nonresponders after week 7 (n=115) B. Placebo; sham titration in nonresponders after week 7 (n=121)	A vs. B Mean age 52 vs. 51 years 62% vs. 60% female Race: 74% vs. 75% white, 20% vs. 17% Hispanic, 6% vs. 7% other Pain, mean BPI 5.9 vs. 6.0 Global health assessment, mean CGI-S 3.2 vs. 3.2	Chronic; mean duration 8.8 vs. 9.5 years	13 weeks

Appendix E13. Data Abstraction of Randomized Controlled Trials of Antidepressants

Author, Year	Results (list results for acute, subacute and chronic separately)	Adverse Events Including Withdrawals	Funding Source	Quality	Comments
Skljarevski 2010 (ENL ref. # 818)	A vs. B Pain, BPI - Severity scale average worst pain mean change from baseline: -2.66 vs. -1.90; p<0.05 Pain, BPI 24-hour Average Pain Score mean change from baseline: -2.08 vs. -1.30; p≤0.01 Function, Brief Pain Inventory - Interference scale, average interference mean change from baseline: -1.92 vs. -1.18; p ≤0.01 Quality of life, Athens Insomnia Scale mean change from baseline: -2.07 vs. -1.49; p=0.38 Quality of life, SF-36 mean between group difference significant for bodily pain (p=0.04), general health (p=0.04) and vitality (p=0.04) subscales favoring duloxetine; no difference for other subscales (data not shown) Return to work, mean between-group difference significant for WPAI work activity impairment subscale (p=0.002) favoring duloxetine; no difference for other subscales (data not shown) Global improvement, CGI-S mean change from baseline: -0.98 vs. -0.77; p=0.14	A vs.B No mortality in either group Serious adverse events: 4% (4/115) vs. 0.8% (1/121); p=0.20 Withdrawals due to adverse events: 14% (16/115) vs. 6% (7/121); p=0.04 Any treatment-emergent adverse event: 57% (65/115) vs. 48% (58/121); p=0.19 Specific adverse events more likely to occur in duloxetine group: nausea (p=0.009), fatigue (p=0.02), hyperhidrosis (p=0.006); specific adverse events more likely to occur in placebo group: headache (p=0.04); no significant difference between groups in incidence of dry mouth, diarrhea, dizziness or constipation	Eli Lilly	Fair	

Please see Appendix C. Included Studies for full study references.

Appendix E14. Trials of Antiseizure Medications Included in the APS/ACP Review

Author, Year, Title	Purpose of Study	Study Design	Inclusion Criteria	Exclusion Criteria	Number of Treatment and Control Subjects (number approached, number eligible, number enrolled)	Subject Age, Gender, Diagnosis
Khoromi, 2005 Topiramate in chronic lumbar radicular pain	To determine the efficacy of topiramate in patients with radiculopathy	RCT with crossover	18-75 years old, lumbar radiculopathy >3 months, severity >=4/10, for at least 5 days a week and with at least one of the following: sharp and shooting pain below knee, pain evoked by straight leg raise to 60 degrees or less, decreased/absent ankle reflex, weakness of muscles below the knee, sensory loss in L5/S1 distribution, electromyographic evidence for L4, L5, of S1 root denitration, MRI showing nerve root compression	Hepatic and renal dysfunction, pregnancy or lactation, seizure disorder, pain of greater intensity in any other location than the low back or leg, opioids and/or drug or alcohol abuse in the past year, fibromyalgia, polyneuropathy and peripheral vascular disease, nephrolithiasis, and narrow angle glaucoma	500 approached, only 45 had radiculopathy 42 enrolled, 21 initially randomized to topiramate, 20 to placebo, 1 postrandomization exclusion (group not reported)	Not reported for initial randomization Overall median age: 53 years (completers) vs. 60 years (drop outs) Female gender: 45% (completers) vs. 50% (drop-outs) Race: Not reported Duration of pain: median 8 years (completers) vs. 4.5 years (drop outs) Baseline pain: 4.04
McCleane, 2001 Does gabapentin have an analgesic effect on background, movement and referred pain? A randomized, double-blind, placebo controlled study	To examine the analgesic effect of gabapentin in patients with radiculopathy.	RCT	Patients with lumbar and associated leg pain, also with paravertebral (not mid-line) lumbar tenderness at one vertebral level and pain worse on extension (not flexion) of the back.	Features of naturopathic pain, adequate control of pain with codeine or NSAIDs, previous treatment or sensitivity to gabapentin	Number approached and eligible not reported 80 enrolled, 40 randomized to gabapentin, 40 to placebo 65 provided 'analyzable' results (31 drug, 34 placebo)	Mean age: 41 vs. 48 years Female gender: 48% (15/31) vs. 48% (21/44) Race: Not reported Duration of pain: 63 vs. 74 months Baseline pain at rest: 6.82 vs. 6.51

Appendix E14. Trials of Antiseizure Medications Included in the APS/ACP Review

Author, Year, Title	Country and Setting	Sponsor	Measures	Type of Intervention	Results
Khoromi, 2005 Topiramate in chronic lumbar radicular pain	USA Outpatient setting	National Institute of Dental and Craniofacial Research and partial support to data technician by Ortho McNeil educational grant	Pain (leg and back): 0 to 10 numeric scale Global pain relief (leg and back pain combined): 6 categorical scales (worse to complete relief) ODI (0 to 100) Beck Depression Inventory SF-36 (0 to 100 on various subscales)	A: Topiramate 50 mg/day titrated to 400 mg/day over 4 weeks, maintained at 400 mg/day from fourth through sixth weeks, followed by crossover to placebo (average dose 208 mg/day) B: Diphenhydramine 6.25 mg/day titrated to max 50 mg/day from third through sixth weeks, followed by crossover to topiramate (average dose 40 mg/day)	Topiramate vs. diphenhydramine, results after 6 weeks of each therapy, compared to baseline (results of initial intervention phase not reported) Average leg pain (0 to 10): -0.98 vs. -0.24 (p=0.06) Average back pain (0 to 10): -1.36 vs. -0.49 (p=0.017) Average overall pain (0 to 10): -0.33 vs. +0.49 (p=0.02) Global pain relief moderate or better: 15/29 (54%) vs. 7/29 (24%) (p=0.005) Global pain relief 'lot' or 'complete': 9/29 (31%) vs. 1/29 (3.4%) ODI: -5 vs. -3 (NS) Beck Depression Inventory: No difference SF-36: No differences for any subscale when corrected for multiple comparisons
McCleane, 2001 Does gabapentin have an analgesic effect on background, movement and referred pain? A randomized, double-blind, placebo controlled study	Ireland Hospital-based pain clinic.	Not reported	Daily self-report on 0 - 10 scale (rate over past 24 hours): average pain at rest, pain on maximal back flexion, leg pain, impression of back mobility. Number of concomitant daily analgesic tablets used daily.	2 weeks no meds, followed by A: Gabapentin 300 mg QD x 1 wk, 600 mg QD x 1 wk, 900 mg QD x 1 wk, 1200 mg QD x 3 weeks B: Placebo	Gabapentin vs. placebo, results at 8 weeks Back pain at rest (0-10 VAS): No change from baseline in either group Back pain with movement (0-10 VAS): -0.47 (p<0.05) vs. +0.01 (NS) Leg pain (0-10 VAS): -0.45 (p<0.05) vs. -0.24 (NS) Mobility scores: No changes Analgesic consumption: -0.45 tablets per day (p=0.05) vs. small increase 2 months after the end of the study, 5 of 40 patients originally receiving gabapentin continued treatment

Appendix E14. Trials of Antiseizure Medications Included in the APS/ACP Review

Author, Year, Title	Duration of Followup	Loss to Followup	Compliance to Treatment	Adverse Events and Withdrawals Due To Adverse Events	Quality Rating	Comments
Khoromi, 2005 Topiramate in chronic lumbar radicular pain	6 weeks each intervention	8/21 (38%) topiramate vs. 4/20 (20%) diphenhydramine dropped out	Not reported	Topiramate vs. diphenhydramine Withdrawal due to adverse events: 7/21 (33%) vs. 3/20 (15%) Any adverse event: 86% vs. 72% Paresthesias: 38% vs. 21% Fatigue/weakness: 34% vs. 31% Sedation: 34% vs. 3% Diarrhea: 30% vs. 10% Headache: 10% vs. 10%		Analysis of potential effects of drop-out bias show no clear effect on conclusions
McCleane, 2001 Does gabapentin have an analgesic effect on background, movement and referred pain? A randomized, double-blind, placebo controlled study	8 weeks	15/80 (19%) did not return for end of study evaluation or did not fill in study forms correctly	Not reported	Gabapentin vs. placebo Withdrawal due to adverse events: None Nausea: 6/31 (19%) vs. 5/34(15%) Drowsiness: 2/31 (6%) vs. 0 Loss of energy: 2/31 (6%) vs. 0 Dizziness: 5/31 (16%) vs. 0		

Appendix E14. Trials of Antiseizure Medications Included in the APS/ACP Review

Author, Year, Title	Purpose of Study	Study Design	Inclusion Criteria	Exclusion Criteria	Number of Treatment and Control Subjects (number approached, number eligible, number enrolled)	Subject Age, Gender, Diagnosis
Muehlbacher, 2006 Topiramate in treatment of patients with chronic low back pain. A randomized, double-blind, placebo-controlled study	To determine the efficacy of topiramate for low back pain with or without leg pain	RCT	LBP > 6 months with or without leg pain but no neurological deficits, >18 years old,	Current acute psychotic or manic episodes, current use of opioids and/or topiramate, significant somatic illness such as cancer, systemic, or cardiopulmonary disease; acute suicidality, alcohol or drug abuse, and pregnancy	Number approached not reported 134 screened 111 eligible 96 enrolled, 48 randomized to topiramate, 48 to placebo	Mean age: 49 vs. 49 years Female gender: 40% vs. 35% Race: Not reported Duration of LBP: 2.5 vs. 2.0 years Baseline Pain Rating Index score: 35.7 vs. 35.9
Yildirim, 2003 The effectiveness of gabapentin in patients with chronic radiculopathy	To determine the efficacy of gabapentin in patients with radiculopathy	RCT	Patients with L5 or S1 lumbosacroradiculopathy	Not stated	Number approached and eligible not reported 50 enrolled, 25 randomized to gabapentin, 25 to placebo.	Mean age: 38 vs. 40 years Female gender: 60% (15/25) vs. 68% (17/25) Race: Not reported Duration of radiculopathy: mean 68 years Unilateral radiculopathy: 84% Bilateral radiculopathy: 16% Spinal MRI: All patients had L4-5 and/or L5-S1 bulging

Appendix E14. Trials of Antiseizure Medications Included in the APS/ACP Review

Author, Year, Title	Country and Setting	Sponsor	Measures	Type of Intervention	Results
Muehlbacher, 2006 Topiramate in treatment of patients with chronic low back pain. A randomized, double-blind, placebo-controlled study	Germany Outpatient setting	Not funded	Pain Rating Index of McGill Pain Questionnaire, German version (0 to 100) State-Trait Anger Expression Inventory (STAXI) ODI (0 to 100) SF-36 (0 to 100 on various subscales)	A: Topiramate 50 mg/day in first week, titrated to 300 mg/day from sixth through tenth weeks (average dose not reported) B: Placebo	Topiramate vs. placebo, results at 10 weeks, compared to baseline Pain Rating Index (0 to 100 scale): -12.9 vs. -1.5 (p<0.001) SF-36 Physical functioning subscale (0 to 100): +8.7 vs. -0.4 (p<0.01, favors topiramate) SF-36, Bodily pain subscale (0 to 100): +4.1 vs. +0.9 (p<0.01, favors topiramate) SF-36, other subscales: Differences in change compared to baseline ranged from 0.6 (Role-emotional) to 8.3 (Role-physical) points, favoring topiramate for all comparisons at p<0.05
Yildirim, 2003 The effectiveness of gabapentin in patients with chronic radiculopathy	Turkey Outpatient setting	Not reported	At baseline, 1 month and 2 months Location of pain Pain at rest (0 to 3 scale) Muscle strength (0 to 5 scale) Limitation of spinal flexion (o to 4 scale) Degree of straight leg raising Stretch reflexes Sensory changes Muscle strength	A: Gabapentin 900 mg/d titrated up to 3600 mg/d in 3 doses for 8 weeks (average dose not reported) B: Placebo	Gabapentin vs. placebo, results at 2 months compared to baseline Pain at rest (0 to 3 scale): -1.04 vs. -0.32 (p<0.01) Muscle strength (0 to 5 scale): +0.52 vs. +0.05 (NS) Sensory changes (0 to 3 scale): -1.12 vs. 0.00 (NS)

Appendix E14. Trials of Antiseizure Medications Included in the APS/ACP Review

Author, Year, Title	Duration of Followup	Loss to Followup	Compliance to Treatment	Adverse Events and Withdrawals Due To Adverse Events	Quality Rating	Comments
Muehlbacher, 2006 Topiramate in treatment of patients with chronic low back pain. A randomized, double-blind, placebo-controlled study	10 weeks	2/48 (4%) topiramate vs. 5/48 (10%) placebo dropped out	Not reported	Topiramate vs. placebo Withdrawal due to adverse events: 2/48 (4%) vs. 2/48 (4%) Severe somnolence: 2/48 vs. 0/48 Vision problems: 2/48 vs. 1/48 Psychomotor slowing: 2/48 vs. 1/48 Memory problems: 2/48 vs. 1/48 Dizziness: 5/48 vs. 3/48 Headache: 4/48 vs. 3/48 Paresthesia and/or tremor: 3/48 vs. 1/48		Also associated with increased weight loss (-6.3 kg, p<0.001) compared to placebo
Yildirim, 2003 The effectiveness of gabapentin in patients with chronic radiculopathy	8 weeks	2/25 (8%) gabapentin vs. 5/25 (20%) placebo dropped out	Not reported	Gabapentin vs. placebo Withdrawal due to adverse events; 2/25 (8%) vs. 0/25		Use of ad hoc outcome Measures

Please see Appendix C. Included Studies for full study references.

Appendix E15. Data Abstraction of Randomized Controlled Trials of Antiseizure Medications

Author, Year	Country Number of Centers and Setting	Inclusion Criteria	Number Randomized, Analyzed Attrition	Intervention	Study Participants	Duration of Pain (acute, subacute, chronic)
Studies published since the APS review						
Baron, 2010	USA, Canada, and Europe Multicenter	≥18 years of age, pain consistent with chronic lumbosacral radiculopathy due to spinal stenosis, leg pain greater than back pain, pain present ≥3 months, stable for ≥4 weeks, mean weekly pain score >4; placebo nonresponder and pregabalin responder (including ≥30% improvement in pain) in run-in period Exclude: Radicular pain for >4 years, surgery for lumbosacral radiculopathy in last 6 months, more than one previous spinal surgery for L5-S1 pain/radiculopathy, epidural injection in last 6 weeks	Randomized: 218 (111 vs. 107) of 378 in run-in period Analyzed: 211 (110 vs. 108) Attrition: 14% (31/218)	Placebo run-in period for 7 days, then pregabalin run-in for 28 days, then: A: Pregabalin: Optimal dose from run-in period (mean 410 mg) x 5 w, then 1 w taper (n=110) B: Placebo: Pregabalin taper x 1 w, then placebo x 4 w, then taper x 1 w (n=108)	Mean age: 52 vs. 53 years Female: 49% vs. 55% Race: Not reported Baseline pain (mean, 0-10 VAS): 6.36 vs. 6.39 Baseline function: Not reported	Chronic (≥3 months); mean duration not reported

Appendix E15. Data Abstraction of Randomized Controlled Trials of Antiseizure Medications

Author, Year	Duration of Followup	Results	Adverse Events Including Withdrawals	Funding Source	Quality Rating
Studies published since the APS review					
Baron, 2010	5 weeks (at end of therapy)	A vs. B Pain (mean change from baseline, 0-10 VAS): -0.16 vs. 0.05 (p=0.33) Pain ≥7/10 (days): 7.1% (8/108) vs. 6.4% (7/107) at 5 w Loss of response (≥1 point increase in weekly mean pain score or use of rescue medication): 27.8% vs. 28.0% at 5 w, HR 0.87 (95% CI 0.52 to 1.47) Medical Outcome Study Sleep Scale sleep disturbance (mean change, 0-100): 2.26 vs. 6.86 (p=0.03) Medical Outcome Study Sleep Scale sleep quantity (mean change, hours): 0 vs. -0.43 (p=0.004) No differences on other MOS Sleep Scale subscales HADS anxiety (mean change, 0-21): -0.19 vs. 0.82 at 5 w (p=0.01) HADS depression (mean change, 0-21): -0.57 vs. 0.56 at 5 w (p=0.0006) EQ-5D, RDQ: No differences, data not reported	A vs. B Any adverse event: 40.9% (45/110) vs. 42.1% (45/107) Serious adverse event: 1.8% (2/110) vs. 0% (0/107) Dizziness: 3.6% (4/110) vs. 1.9% (2/107) Somnolence: 0.9% (1/110) vs. 0.9% (1/107) Edema: 4.5% (5/110) vs. 1.9% (2/107)	Pfizer Inc.	Fair

Appendix E15. Data Abstraction of Randomized Controlled Trials of Antiseizure Medications

Author, Year	Country Number of Centers and Setting	Inclusion Criteria	Number Randomized, Analyzed Attrition	Intervention	Study Participants	Duration of Pain (acute, subacute, chronic)
Baron, 2014	Europe Multicenter	≥18 years of age, chronic (≥3 months) low back pain requiring a WHO step III analgesic (baseline pain thresholds specified for persons on step I or 2 analgesics), painDETECT score for neuropathic pain ≥13 (0 to 38 scale), tapentadol responder during run-in period Exclude: Pregnant, breastfeeding, back pain due to cancer, painful procedure planned, other pain condition, comorbid conditions, alcohol or drug abuse, allergy or sensitivity to study drugs	Randomized: 313 (159 vs. 154) of 313 in run-in period Analyzed: 309 (157 vs. 152) Attrition: 17% (56/313)	Washout for 3-14 days, then tapentadol PR run-in for 3 weeks, then: A: Pregabalin + tapentadol PR: Pregabalin 150 mg/day x 1 w, 300 mg/day x 7 w + tapentadol PR 300 mg/day (n=157) B: Tapentadol PR: Tapentadol 300 mg/day + 100 mg/day x 1 w, tapentadol 300 mg/day + 200 mg/day x 7 w (n=152)	Mean age: 56 vs. 58 years Female: 54% vs. 62% White: 99% vs. 100% Baseline pain: 5.9 vs. 5.9 (at randomization) Baseline function: Not reported	Chronic (≥ 3 months): mean 8.7 vs. 9.4 years

Appendix E15. Data Abstraction of Randomized Controlled Trials of Antiseizure Medications

Author, Year	Duration of Followup	Results	Adverse Events Including Withdrawals	Funding Source	Quality Rating
Baron, 2014	9-10 weeks (1-2 weeks after end of therapy)	A vs. B Pain (mean change from baseline, 0-10 VAS): -1.6 vs. -1.7 at 9-10 w (p>0.05) Leg pain (mean change from baseline, 0-10 VAS): -1.6 vs. -1.9 at 9-10 w Patient satisfaction good, very good, or excellent: 73% (114/157) vs. 67% (102/152) at 9-10 w "Minimally", "much", or "very much" improved: 82% (129/157) vs. 81% (123/152) at 9-10 w SF-12: No difference on any subscale at 9-10 w EQ-5D (mean, 0-10): 0.60 vs. 0.61 at 9-10 w HADS anxiety (mean): 5.8 vs. 6.0 at 9-10 w HADS depression (mean): 5.4 vs. 6.2 at 9-10 w	A vs. B Any adverse events: 65% (103/159) vs. 64% (98/154) Discontinued due to adverse events: 7.5% (12/158) vs. 7.8% (12/154) Dizziness: 17.6% vs. 11.0% Somnolence: 11.9% vs. 8.4% Nausea: 9.4% vs. 10.4% Headache: 8.2% vs. 6.5% Constipation: 5.0% vs. 7.1% Dry mouth: 5.0% vs. 3.9%		Fair

Appendix E15. Data Abstraction of Randomized Controlled Trials of Antiseizure Medications

Author, Year	Country Number of Centers and Setting	Inclusion Criteria	Number Randomized, Analyzed Attrition	Intervention	Study Participants	Duration of Pain (acute, subacute, chronic)
Markman, 2014	USA Single center	≥50 years of age, radiographically confirmed lumbar spinal stenosis with neurogenic claudication for ≥3 months (inducible pain ≥4/10 within 15 minutes of treadmill ambulation) Exclude: Previous pregabalin, prior surgery for lumbar spinal stenosis, vascular disease, movement disorder, neurologic disease impacting ambulation, moderate or severe arthritis of knee or hip, serious medical comorbidities, allergy to diphenhydramine, severe psychiatric disorder	Randomized: 29 (14 vs. 15) Analyzed: 26 (14 vs. 12) Attrition: 10% (3/29)	A: Pregabalin: 75 mg po bid x 3 d, 150 mg bid x 7 d, 75 mg bid x 4 d (n=14) B: Placebo: Diphenhydramine 6.25 mg po bid x 3 d, 12.5 mg bid x 7 d, 6.25 mg bid x 4 d (n=12) Each treatment for 2 weeks, with 1 week washout	Mean age: 71 vs. 69 years Female: 29% vs. 33% White: 100% vs. 93% Baseline pain with ambulation (mean, 0-10 NRS): 7.7 vs. 7.1 Baseline RDQ (mean, 0-24): 13 vs. 14	Chronic (≥3 months): 84% vs. 93% >12 months

Appendix E15. Data Abstraction of Randomized Controlled Trials of Antiseizure Medications

Author, Year	Duration of Followup	Results	Adverse Events Including Withdrawals	Funding Source	Quality Rating
Markman, 2014	10 days (prior to tapering of each treatment)	A vs. B Walking distance (mean, m): 237 vs. 261 at 2 w (p=0.35) Pain with ambulation (mean, 0-10 NRS): 7.22 vs. 6.97 at 2 w (p=0.46) RDQ (mean, 0-24): 13 vs. 11 at 2 w (p=0.01) Brief Pain Inventory-Short Form, interference (mean, 0-10): 3.7 vs. 3.58 at 2 w (p=0.68) BPI-SF, pain intensity (mean, 0-10): 4.4 vs. 4.5 at 2 w (p=0.68) ODI (mean, 0-100): 38 vs. 36 at 2 w (p=0.36) Swiss Spinal Stenosis Questionnaire, symptom severity (mean): 3.09 vs. 2.94 at 2 w (p=0.07) Swiss Spinal Stenosis Questionnaire, physical function (mean): 2.40 vs. 2.45 at 2 w (p=0.57)	A vs. B Any adverse events: 64% (19/28) vs. 35% (9/26) Serious adverse events: None Withdrawal due to adverse events: 7.1% (2/28) vs. 0% (0/26) Dizziness: 43% (12/28) vs. 3.8% (1/26) Diarrhea: 11% (3/28) vs. 7.7% (2/26) Somnolence: 18% (5/28) vs. 7.7% (2/26) Dry mouth: 14% (4/28) vs. 0% (0/26) Nausea: 11% (3/28) vs. 15% (4/26) Edema: 18% (5/28) VS. 7.7% (2/26)	Pfizer Inc.	Fair

Appendix E15. Data Abstraction of Randomized Controlled Trials of Antiseizure Medications

Author, Year	Country Number of Centers and Setting	Inclusion Criteria	Number Randomized, Analyzed Attrition	Intervention	Study Participants	Duration of Pain (acute, subacute, chronic)
Pota, 2012	Italy Single center	35 to 80 years of age, chronic mechanical-degenerative back pain, symptoms began 12 to 60 months prior, pain ≥50 on 0-100 VAS and >20 on the Pain Rating Index of the Short-Form McGill Pain Questionnaire Exclude: Neurological and neuromuscular conditions, other comorbid conditions, hypersensitivity to study drugs, psychiatric disease, HIV infection or other immunodeficiency, skin conditions preventing patch application, cancer-related back pain, pregnant or lactating, renal or liver failure	Randomized: 44 (22 vs. 22) of 44 in run-in period Analyzed: 44 Attrition: 0%	Buprenorphine run-in period for 3 weeks, then: A: Pregabalin 300 mg/day + transdermal buprenorphine 35 mcg/h x 3 w (n=22) B: Placebo + transdermal buprenorphine 35 mcg/h x 3 w (n=22)	Mean age: 56 years (overall) Female: 50% (overall) Race: Not reported Baseline pain (mean, 0-100 VAS): 35 vs. 32 Baseline function: Not reported	Chronic (12 to 60 months); mean 15 months

Appendix E15. Data Abstraction of Randomized Controlled Trials of Antiseizure Medications

Author, Year	Duration of Followup	Results	Adverse Events Including Withdrawals	Funding Source	Quality Rating
Pota, 2012	3 weeks (at end of therapy)	A vs. B Pain (mean, 0-100 VAS): 9.5 vs. 32.8 at 1 w, 6.1 vs. 32.8 at 2 w, 5.7 vs. 33.3 ($p<0.05$) at 3 w Short-Form McGill Pain Questionnaire Pain Rating Index (mean, 0-15): 9.2 vs. 16.5 at 1 w, 4.6 vs. 16.6 at 2 w, 3.7 vs. 16.2 at 3 w ($p<0.05$) SF-MPQ Present Pain Intensity (mean, 0-5): 0.4 vs. 1.7 at 1 w, 0.3 vs. 1.8 at 2 w, 0.3 vs. 2.0 at 3 w Sleep interference (mean, 0-10): 0.2 vs. 2.3 at 1 w, 0.7 vs. 1.8 at 2 w, 0.6 vs. 1.9 at 3 w ($p>0.05$) Acetaminophen use (mean, mg): 46 vs. 636 at w 3 ($p<0.05$)	A vs. B Withdrawal due to adverse events: None Constipation: 23% (5/22) vs. 14% (3/22) Nausea: 14% (3/22) vs. 14% (3/22) Dizziness: 0% (0/22) vs. 14% (3/22) Somnolence: 18% (4/22) vs. 23% (5/22)	Reports no funding	Fair

Appendix E15. Data Abstraction of Randomized Controlled Trials of Antiseizure Medications

Author, Year	Country Number of Centers and Setting	Inclusion Criteria	Number Randomized, Analyzed Attrition	Intervention	Study Participants	Duration of Pain (acute, subacute, chronic)
Romano, 2009	Italy Single center	18 to 75 years of age; chronic (>6 months) low back pain due to disc prolapse, lumbar spondylosis, and/or spinal stenosis; pain VAS >40 Exclude: Prior back surgery, diabetes, neurological disease, cardio-renal disease history of gastric ulcers or gastrointestinal bleeding, allergy to study drugs, alcohol or drug abuse	Randomized: 42 Analyzed: 36 (12 vs. 12 vs. 12) Attrition: 14% (6/42)	A: Pregabalin ~1 mg/kg/d x 1 w, then 2-4 mg/kg/d (mean 2.1 mg/kg/d) (n=12) B: Celecoxib ~3-6 mg/kg/d (mean 4.2 mg/kg/d) (n=12) C: Pregabalin + celecoxib (mean 1.78 and 3.75 mg/kg/d) (n=12) Each treatment for 4 weeks, with 1 week washout prior to crossover	Mean age: 53 years (overall) Female: 56% (overall) Race: Not reported Baseline pain: Not reported for initial intervention (mean 45-48) Baseline function: Not reported for initial intervention Disc prolapse: 47% Lumbar spondylosis: 39% Spinal stenosis: 19%	Chronic (>6 months); mean duration not reported
Yaksi, 2007	Turkey Single center	Lumbar spinal stenosis (central or lateral recess) confirmed on CT or MRI Exclude: Other pain syndromes	Randomized: 55 (28 vs. 27) Analyzed: Unclear Attrition: Not reported	A: Gabapentin: initial dose 300 mg/day, titrated up to 2400 mg/day (mean not reported) (n=28) B: No gabapentin (n=27) Both groups also received exercise, lumbar corset, and NSAIDS; duration of treatment 4 months	Mean age: 51 vs. 51 years Female: 79% vs. 56% Race: Not reported Baseline pain (mean, 0-10 VAS): 7.0 vs. 6.7 Baseline function: Not reported	Duration not specified

Appendix E15. Data Abstraction of Randomized Controlled Trials of Antiseizure Medications

Author, Year	Duration of Followup	Results	Adverse Events Including Withdrawals	Funding Source	Quality Rating
Romano, 2009	4 weeks (at end of each treatment period)	A vs. B vs. C Pain (mean, 0-100 VAS): 43 vs. 40 vs. 29 at 4 w (p=0.0001 for A vs. C and p=0.001 for B vs. C) Pain reduction: 10% vs. 12% vs. 38% at 4 w Leeds Assessment of Neuropathic Symptoms and Signs (LANSS) score <12 Pain (mean, 0-100 VAS): 50.7 vs. 32.5 vs. 32.9 at 4 w (p=0.0002 for A vs. C and p=0.9 for B vs. C) Pain reduction (estimated from graph): -2.5% vs. 26% vs. 27% at 4 w LANSS score >12 Pain (mean, 0-100 VAS): 36.3 vs. 32.5 vs. 23.1 (p=0.01 for A vs. C and p=0.0001 for B vs. C) Pain reduction (estimated from graph): 23% vs. 2% vs. 52%	A vs. B vs. C Withdrawal due to adverse events: 9% (4/42) overall (not reported by group) Side effects: 14% (5/36) vs. 11% (4/36) vs. 19% (7/36)	Not reported	Fair
Yaksi, 2007	4 months (at end of therapy)	A s. B Pain (mean, 0-10 VAS): 5.1 vs. 5.6 at 1 m (p=0.40), 4.3 vs. 5.0 at 2 m (p=0.12), 3.6 vs. 4.8 at 3 m (p=0.04), 2.9 vs. 4.7 at 4 m (p=0.006) Walking distance >1000 m (estimated from graph): 65% vs. 21% at 4 m (p=0.001) Sensory deficit: 32% (9/28) vs. 63% (17/27)	A vs. B Withdrawal due to adverse events: None Ataxia: 7.1% (2/28) vs. not reported	Reports no funding	Poor

Please see Appendix C. Included Studies for full study references.

Appendix E16. Trials of Corticosteroids Included in the APS/ACP Review

Author, Year, Title	Purpose of Study	Study Design	Inclusion Criteria	Exclusion Criteria	Number of Treatment and Control Subjects (number approached, number eligible, number enrolled)
Finckh, 2006 Short-term efficacy of intravenous pulse glucocorticoids in acute discogenic sciatica. A randomized controlled trial	To evaluate the short-term efficacy of a single large intravenous dose of glucocorticoids on the symptoms of acute discogenic sciatica	RCT	Age >16 years, hospitalized for acute sciatica, duration >1 weeks and less than 6 weeks	Contraindications to steroids, major motor impairment or cauda equina syndrome, history of lumbar surgery, primary lumbar spinal stenosis, pregnancy, inability to read the consent form, prior treatment for sciatic with glucocorticoids	Number approached and eligible not reported 65 randomized 60 completed treatment and followup assessments
Friedman, 2006 Parenteral corticosteroids for emergency department patients with nonradicular low back pain	To evaluate the efficacy of a single injection of corticosteroids in patients with low back pain and a negative straight leg raise test	RCT	Age 21 to 50 years, nontraumatic low back pain, seen in emergency room, negative straight leg raise test	Cancer or infection suspected, pregnancy, lactation, allergy or intolerance to study medication, another episode of low back pain within last 4 weeks, recent systemic steroid use, history of back surgery, metastatic cancer, chronic pain syndrome, inflammatory arthritis, or suspected vascular, urologic, or gynecologic pathology	Number approached not reported 107 eligible 87 randomized (44 to steroid, 43 to placebo)
Haimovic, 1986 Dexamethasone is not superior to placebo for treating lumbosacral radicular pain	To evaluate the efficacy of a course of oral dexamethasone for lumbosacral radicular pain	Controlled clinical trial (not clear if randomized)	Patients admitted for lumbosacral radicular pain	Neoplastic disease or know cause of pain other than degenerative disease of the lumbosacral spine or intervertebral disks	Number approached and eligible not reported 33 randomized
Porsman, 1979 Prolapsed lumbar disc treated with intramuscularly administered dexamethasone phosphate	To evaluate the efficacy of a course of intramuscular dexamethasone for lumbosacral radicular pain	Controlled clinical trial (not clear if randomized)	Patients admitted with at least 4 of 6 pre-specified symptoms of prolapsed lumbar disc	Not stated	Number approached and eligible not reported 52 enrolled 49 evaluated

Appendix E16. Trials of Corticosteroids Included in the APS/ACP Review

Author, Year, Title	Subject Age, Gender, Diagnosis	Country and Setting	Sponsor	Measures
Finckh, 2006 Short-term efficacy of intravenous pulse glucocorticoids in acute discogenic sciatica. A randomized controlled trial	Age: mean 49.0 vs. 45.4 Female: 45% vs. 59% Race: Not reported Concomitant NSAID: 26% vs. 24% VAS leg pain (0-100): 67 vs. 63 VAS back pain (0-100): 47 vs. 55 VAS global pain (0-100): 65 vs. 61 Neurologic deficits: 52% vs. 34% Duration of pain (median): 15 days vs. 15 days	Switzerland Hospitalized patients	None	Sciatic pain: VAS (0-100) Low back pain: VAS (0-100) Global pain: VAS (0-100) and McGill Pain Questionnaire Functional disability: Oswestry questionnaire Straight leg raise Lumbar flexion: Schober test Concomitant analgesic medication Additional glucocorticoids after day 3
Friedman, 2006 Parenteral corticosteroids for emergency department patients with nonradicular low back pain	Age: mean 36 vs. 36 years Female gender: 64% vs. 54% Non-white race: 88% vs. 93% Duration of back pain (hours): 44 vs. 63 Baseline back pain severity (0 to 10): 8.6 vs. 9.1	U.S. Emergency room	Not reported	Pain: numerical pain rating scale (0 to 10) and 4-point categorical scale (none, mild, moderate, or severe) Roland Morris-18 (modified RDQ): 0 to 18
Haimovic, 1986 Dexamethasone is not superior to placebo for treating lumbosacral radicular pain	Age, gender, race: Not reported Duration of pain not reported Resting low back pain: 100% vs. 100% Focal weakness or sensory loss: 76% vs. 92%	U.S. Hospitalized patients	Not reported	Early improvement: Defined as resting LBP or radicular pain on SLR reported as 'definitely less' than before treatment Late or sustained improvement: Defined as pain score of 3 or less (0 to 6 scale)
Porsman, 1979 Prolapsed lumbar disc treated with intramuscularly administered dexamethasone phosphate	Age: mean 47.1 vs. 42.1 years Female: 32% vs. 33% Race: Not reported Average duration of hospitalization: 22 vs. 21 days Severity and duration of pain not reported	Denmark Hospitalized patients	Not reported	Not specified

Appendix E16. Trials of Corticosteroids Included in the APS/ACP Review

Author, Year, Title	Type of Intervention	Results	Duration of Followup
Finckh, 2006 Short-term efficacy of intravenous pulse glucocorticoids in acute discogenic sciatica. A randomized controlled trial	A: Methylprednisolone 500 mg IV bolus B: Placebo IV	Methylprednisolone IV bolus vs. placebo Leg pain: Methylprednisolone superior at day 3 (p=0.04), but magnitude small (5.7 mm, 95% CI 0.3 to 10.9); no differences after first 3 days Proportion of responders (decrease in VAS >=20 mm) at day 1: 48% vs. 28% (p=0.097) No differences for low back pain, global pain, straight leg raise, lumbar flexion, functional disability, proportion requiring spine surgery within the first month (5% vs. 1.7%), analgesic use, or subsequent glucocorticoid use	30 days
Friedman, 2006 Parenteral corticosteroids for emergency department patients with nonradicular low back pain	A: Methylprednisolone 160 mg IM B: Placebo IM Both groups received naproxen 500 mg (14 tablets), oxycodone 5 mg/acetaminophen 325 mg (12 tablets)	Methylprednisolone IM vs. placebo Pain, mean change from baseline (0 to 10 scale): -4.1 vs. -4.8 (NS) after 1 week, -5.1 vs. -5.8 (NS) after 1 month RDQ-18, mean score (0 to 18): 2.6 vs. 3.4 after 1 week, 2.6 vs. 3.1 after 1 month	1 month
Haimovic, 1986 Dexamethasone is not superior to placebo for treating lumbosacral radicular pain	A: Dexamethasone 64 mg (day 1), 32 mg (day 2), 16 mg (day 3), 12 mg (day 4), and 8 mg (days 5-7) po B: Placebo	Dexamethasone vs. placebo Early improvement: 33% (7/21) vs. 33% (4/12) Late improvement (1 year): 29% (6/21) vs. 33% (4/12) Sustained improvement (1 to 4 years): 50% (8/16) vs. 64% (7/11)	1 to 4 years
Porsman, 1979 Prolapsed lumbar disc treated with intramuscularly administered dexamethasone phosphate	A: Dexamethasone 64 mg (day 1), 32 mg (day 2), 24 mg (day 3), 12 mg (day 4), and 8 mg (days 5-7) IM B: Placebo	Dexamethasone vs. placebo "Effect": 52% (13/25) vs. 58% (14/24) Hospitalization: 21.9 vs. 21.0 days Subsequent surgery: 32% (8/25) vs. 25% (6/24)	9 days or longer

Appendix E16. Trials of Corticosteroids Included in the APS/ACP Review

Author, Year, Title	Loss to Followup	Compliance to Treatment	Adverse Events and Withdrawals Due To Adverse Events	Quality Rating	Comments
Finckh, 2006 Short-term efficacy of intravenous pulse glucocorticoids in acute discogenic sciatica. A randomized controlled trial	5 (2 withdrew consent after randomization and 3 refused followup evaluations)	All assigned patients received methylprednisolone dose	Methylprednisolone group: 2 transient hyperglycemia and 1 facial flush		Only single bolus dose in hospitalized patients; short-term followup
Friedman, 2006 Parenteral corticosteroids for emergency department patients with nonradicular low back pain	1 subject at month	Not reported, assumed complete	Methylprednisolone vs. placebo Hyperglycemia requiring medical attention, infection, or GI bleeding: None Any adverse medication effect: 21% vs. 45% ($p<0.05$) Upper GI adverse effect: 8% vs. 21%		
Haimovic, 1986 Dexamethasone is not superior to placebo for treating lumbosacral radicular pain	All evaluated at 1 year; 6 lost to long term followup (5 dexamethasone and 1 placebo)	Not reported	Not reported		Not clear if randomized
Porsman, 1979 Prolapsed lumbar disc treated with intramuscularly administered dexamethasone phosphate	3 patients excluded from analyses (1 protocol violation, 2 stopped medication due to side effects)	Not reported	Withdrawal due to adverse events: 4% (1/25) vs. 4% (1/24)		Not clear if randomized

Please see Appendix C. Included Studies for full study references.

Appendix E17. Data Abstraction of Randomized Controlled Trials of Corticosteroids

Author, Year	Country Number of Centers and Setting	Inclusion Criteria	Number Randomized, Analyzed Attrition	Intervention	Study Participants	Duration of Pain (acute, subacute, chronic)
Eskin, 2014	USA Single center	18 to 55 years of age, musculoskeletal low back pain from bending or twisting within 48 hours, ≥5 on 0-10 VAS Exclude: Blunt trauma, neurological motor deficits, neoplastic disease, fever, pregnant, current use of steroids of other immunosuppressant, diabetes, uncontrolled hypertension, significant peptic ulcer disease, cataracts, urinary tract infection, allergy to prednisone, lactose intolerance, visits from occupational medicine program	Randomized: 79 (39 vs. 40) Analyzed: 67 (32 vs. 35) Attrition: 15% (12/79)	A: Prednisone: 50 mg po QD x 5 days (n=32) B: Placebo (n=35)	Mean age: 39 vs. 41 years Female: 33% vs. 27% Race: Not reported Baseline pain (mean, 0-10 VAS): 8.0 vs. 8.0 Baseline function: Not reported	Acute (<2 days)

Appendix E17. Data Abstraction of Randomized Controlled Trials of Corticosteroids

Author, Year	Duration of Followup	Results	Adverse Events Including Withdrawals	Funding Source	Quality Rating
Eskin, 2014	5-7 days (treatment 5 days)	A vs. B vs. C Pain (mean, 0-3 VRS): 1.3 vs. 1.1 at 5-7 d (difference 0.2, 95% CI -0.2 to 0.6) No or mild pain: 56% vs. 69% (difference -13%, 95% -36% to 10%) Days of work lost (mean): 2.1 vs. 1.3 (p=0.06) Sought further care: 40% vs. 18% (difference 22%, 95% CI 0% to 43%)	"No significant side effects"	Emergency Medical Associates Research Foundation	Fair

Appendix E17. Data Abstraction of Randomized Controlled Trials of Corticosteroids

Author, Year	Country Number of Centers and Setting	Inclusion Criteria	Number Randomized, Analyzed Attrition	Intervention	Study Participants	Duration of Pain (acute, subacute, chronic)
Friedman, 2008	USA Single center	21 to 50 years of age, non-radicular low back pain for ≤1 week Exclude: Back pain episode in last month, positive straight leg raise test, fever, cancer with metastatic risk, recent blunt trauma to back, chronic pain syndrome, history of spinal surgery, inflammatory arthritis, recent use of corticosteroids, use of pain medication daily or near daily, pregnant or lactating, allergy to study medications	Randomized: 82 (39 vs. 43) Analyzed: 78 (37 vs. 41) Attrition: 4.9% (4/82)	A: Methylprednisolone: 160 mg IM x 1 (n=37) B: Placebo (n=41)	Mean age: 39 vs. 37 years Female: 54% vs. 51% Hispanic/Latino: 69% vs. 67% African-American/Black: 22% vs. 21% White: 8% vs. 7% Baseline pain (0-10 VAS): 8.9 vs. 9.1 Baseline function: Not reported	Acute (<1 week), median 48 hours
Hedeboe, 1982	Denmark Single center	4 of the following: Radicular pain, paresthesia, paresis, sensory change, decreased tendon reflexes, positive straight leg raise Exclude: Psychiatric conditions, cardiac disease, hypertension, diabetes, prior spinal surgery	Randomized: 39 (19 vs. 20) Analyzed: 39 Attrition: Not reported	A: Dexamethasone: 4 mg/ml, 16 mg IM QID x 1 d, 8 mg QID x 1 d, 8 mg tid x 1 d, 4 mg tid x 1 d, 4 mg bid on x 3 d (N=19) B: Placebo (n=20)	Mean age: 44 vs. 40 years Female: 47% vs. 25% Race: Not reported Baseline pain: Not reported Baseline function: Not reported	Duration not specified

Appendix E17. Data Abstraction of Randomized Controlled Trials of Corticosteroids

Author, Year	Duration of Followup	Results	Adverse Events Including Withdrawals	Funding Source	Quality Rating
Friedman, 2008	1 month (single treatment in ER)	A vs. B Improvement in pain (mean, 0-10 VAS): difference 1.1 (95% CI -0.5 to 2.8) at 1 w; 7.1 vs. 5.8 at 1 m, difference 1.3 (95% CI -0.2 to 2.7) Back pain in prior 24 hours: 46% vs. 61% at 1 m, OR 0.54 (95% CI 0.22 to 1.3) Analgesic use in past 24 hours: 22% vs. 43% at 1 m, OR 0.39 (95% CI 0.14 to 1.1) RDQ18 (median, 0-18): 0 vs. 0 (p=0.009) RDQ18 1 or higher: 42% vs. 46% at 1 w; 19% vs. 49% at 1 m, OR 0.25 (95 5CI 0.09 to 0.7) Not resumed usual activities: 14% vs. 23% at 1 m, OR 0.56 (95% CI 0.17 to 1.9) Not resumed work (among full-time workers): 8% (2/24) vs. 13% (3/24) at 1 m, OR 0.64 (95% CI 0.10 to 4.2) Did not seek additional health care: 67% vs. 59% at 1 m, difference 8% (95% CI -14% to 30%)	A vs. B Any adverse event: 32% vs. 24% at 1 w, difference 9% (95% CI -12% to 30%) No gastrointestinal bleeding, osteonecrosis, infection, hyperglycemia, need for additional treatment due to study drugs	Reports no funding	Good
Hedeboe, 1982	3 months (treatment 7 days)	A vs. B Clear improvement (not otherwise defined): 68% (13/19) vs. 35% (7/20) at 9 d, RR 1.95, 95% CI 1.0 to 3.82; 32% (6/19) vs. 25% (5/20) at 3 m, RR 1.26, 95% CI 0.46 to 3.46	A vs. B Withdrawal due to adverse events: 0% (0/19) vs. 0% (0/20) Any side effect: 32% (6/19) vs. 5.0% (1/20) at 1 w, RR 6.32, 95% CI 0.84 to 47.7	Not reported	Fair

Appendix E17. Data Abstraction of Randomized Controlled Trials of Corticosteroids

Author, Year	Country Number of Centers and Setting	Inclusion Criteria	Number Randomized, Analyzed Attrition	Intervention	Study Participants	Duration of Pain (acute, subacute, chronic)
Holve, 2008	USA Single center	20 to 60 years of age, acute (<1 week) sciatica (unilateral leg pain extending below knee and positive straight leg raise) Exclude: Pregnant, diabetes, renal failure, upper gastrointestinal bleeding, major psychiatric disease, red flag symptoms	Randomized: 29 (15 vs. 14) Analyzed: 27 (13 vs. 14) Attrition: 6.9% (2/29)	A: Prednisone: 60 mg po QD x 3 d, 40 mg po QD x 3 d, 20 mg po QD x 3 d (n=13) B: Placebo (n=14)	Mean age: 39 vs. 46 years Female: 37% (overall) Race: Not reported Baseline Roland Morris pain (mean, 0-5 VRS): 3.8 vs. 3.1 Baseline RDQ (mean, 0-24): 16 vs. 16	Acute (<1 week)

Appendix E17. Data Abstraction of Randomized Controlled Trials of Corticosteroids

Author, Year	Duration of Followup	Results	Adverse Events Including Withdrawals	Funding Source	Quality Rating
Holve, 2008	6 months (treatment 9 days)	A vs. B Roland Morris Pain (mean, 0-5 Rolad Morris pain, estimated from graph): 2.5 vs. 2.6 at 1 w, 1.8 vs. 2.1 at 2 w, 1.6 vs. 1.6 at 4 w, 1.5 vs. 1.0 at 3 m, 0.4 vs. 1.6 at 6 m (p>0.05) RDQ (mean, 0-24): 13 vs. 16 at 1 w, 8 vs. 13 at 2 w, 8 vs. 9 at 4 w, 3 vs. 2 at 3 m, 1 vs. 2 at 6 m (p>0.05) Return to baseline work hours: ~60% in each group by 2 m (p>0.05) NSAID and opioid use: No differences, data not provided Epidural injections: 15% (2/13) vs. 43% (6/14), RR 0.36 (95% CI 0.9 to 1.47)	Not reported	Kaiser Foundation Research Institute	Poor

Please see Appendix C. Included Studies for full study references.

Appendix E18. Trials of Exercise Included in the APS/ACP Review

Author, Year, Title	Purpose of Study	Study Design	Inclusion Criteria	Exclusion Criteria	Number of Treatment and Control Subjects (number approached, number eligible, number enrolled)
UK BEAM Trial team, 2004 United Kingdom back pain exercise and manipulation (UK BEAM) randomized trial: effectiveness of physical treatments for back pain in primary care	To evaluate the efficacy of spinal manipulation, exercise, both, or usual 'best care' in patients with low back pain	RCT	Low back pain with or without radiation mainly above knee, age 18 to 65, score of four or more on Rolad disability questionnaire, pain every day for 28 days before enrollment or for 21 out of 28 days before randomization and 21 out of 28 days before that, agreed to avoid other physical treatments for three months	Possibility of serious spinal disorder, pain below knee, previous spinal surgery, another more troublesome musculoskeletal disorder, previous treatment in pain management clinic, severe psychiatric disorder, another important medical condition, severe hypertension, anticoagulant treatment, long term steroids, unable to walk >100 m when free of back pain, unable to get up and down to floor, physical therapy in last 3 months	7917 approached 4052 eligible 1334 randomized (333 to manipulation + exercise, 353 to manipulation, 310 to exercise, and 338 to usual care)

Appendix E18. Trials of Exercise Included in the APS/ACP Review

Author, Year, Title	Subject Age, Gender, Diagnosis	Country and Setting	Sponsor	Measures
UK BEAM Trial team, 2004 United Kingdom back pain exercise and manipulation (UK BEAM) randomized trial: effectiveness of physical treatments for back pain in primary care	Mean age: 43 years Female gender: 56% Non-white race: 4% Current episode >90 days: 59% Roland disability score: 9.0	UK Multicenter Primary care	Medical Research Council, National Health Service	Roland Disability Questionnaire Von Korff scale Back Beliefs questionnaire Fear Avoidance Beliefs Questionnaire SF-36 EuroQol

Appendix E18. Trials of Exercise Included in the APS/ACP Review

Author, Year, Title	Type of Intervention	Results	Duration of Followup
UK BEAM Trial team, 2004 United Kingdom back pain exercise and manipulation (UK BEAM) randomized trial: effectiveness of physical treatments for back pain in primary care	A: Manipulation + exercise B: Manipulation (up to 8 twenty minute sessions over 12 weeks) C: Exercise (individual assessment followed by group classes incorporating cognitive behavioral principles, up to 8 sixty minute sessions over 4 to 8 weeks and a 'refresher' class at 12 weeks) D: Usual care (based on UK national acute back pain guidelines)	Net benefit from manipulation + exercise, manipulation, and exercise vs. usual care alone at 12 months Roland (0 to 24 scale): 1.30 (0.54 to 2.07) vs. 1.01 (0.22 to 1.81) vs. 0.39 (-0.41 to 1.19) Modified Von Korff pain (0 to 100 scale): 6.71 (2.47 to 10.95) vs. 5.87 (1.58 to 10.17) vs. 4.90 (0.30 to 9.50) Modified Von Korff disability (0 to 100 scale): 6.71 (2.62 to 10.80) vs. 5.65 (1.57 to 9.72) vs. 4.56 (0.34 to 8.78) Fear avoidance beliefs questionnaire-physical scale (0 to 24 scale): 1.24 (0.07 to 2.41) vs. -0.10 (-1.09 to 0.89) vs. 1.08 (-0.05 to 2.22) Back beliefs questionnaire (9 to 45 scale): 2.96 (1.84 to 4.07) vs. 1.43 (0.33 to 2.54) vs. 1.46 (0.33 to 2.58) SF-36 physical component (0 to 100): 2.53 (0.96 to 4.09) vs. 1.68 (0.18 to 3.19) vs. 1.55 (-0.02 to 3.11) SF-36 mental component (0 to 100): 1.30 (-0.55 to 3.14) vs. 1.68 (-0.21 to 3.57) vs. 0.34 (-1.69 to 2.37)	12 months

Appendix E18. Trials of Exercise Included in the APS/ACP Review

Author, Year, Title	Loss to Followup	Compliance to Treatment	Adverse Events and Withdrawals Due To Adverse Events	Quality Rating	Comments
UK BEAM Trial team, 2004 United Kingdom back pain exercise and manipulation (UK BEAM) randomized trial: effectiveness of physical treatments for back pain in primary care	26% at 1 year, 23% at 3 months	Not clear	"No serious adverse events"		In a cost utility analysis (UK BEAM Trial Team, BMJ 2005, doi:10.1136/bmj.38282.607859.AE), compared top best care in general practice the incremental cost-effectiveness of manipulation + exercise was 3800 pounds/QALY (dominates exercise alone), manipulation alone 4800 pounds/QALY, and exercise alone 8300 pounds/QALY;

Please see Appendix C. Included Studies for full study references.

Appendix E19. Data Abstraction of Systematic Reviews of Exercise

Author, Year	Comparison	Data Sources	Number and Type of Studies	Interventions and Number of Patients	Methods for Rating Methodological Quality of Primary Studies
van Middelkoop 2010	1) Exercise vs wait list/no treatment; 2) Exercise vs usual care; 3) Exercise vs back school/education; 4) Exercise vs other forms of exercise therapy	All trials of the Cochrane review (Hayden 2005) and updated search thru December 22, 2008: MEDLINE, EMBASE, CINAHL, CENTRAL and PEDro databases; language restriction NR	37 RCTs (N = 3957) chronic (≥12 weeks) nonspecific LBP post-treatment, short, intermediate, and long-term followup (not defined)	1) A: Exercise versus B:wait list/no treatment (8 trials) 2) A: Exercise versus C: usual care (6 trials) 3) A: Exercise versus D: back school/education (3 trials) 4) A: Exercise versus E: other forms of exercise therapy (11 trials)	GRADE

Appendix E19. Data Abstraction of Systematic Reviews of Exercise

Author, Year	Methods for Synthesizing Results of Primary Studies	Results	Adverse Events	Quality
van Middelkoop 2010	NR	A vs B Pain intensity, pooled mean differences (95% CI) Post-treatment (5 trials, n = 268) : −4.51 (–9.49 to 0.47) Intermediate (2 trials, n = 137) : −16.46 (–44.48 to 11.57) Long-term (1 trial, n = 102): NS (no data reported) Disability, pooled mean differences (95% CI) Post-treatment (6 trials, n = 331: −3.63 (–8.89 to 1.63) Intermediate (1 trial, n = 102): NS (no data reported) Long-term (1 trial, n = 102): NS (no data reported) A vs C Pain intensity, weighted mean difference (95% CI) Post-treatment (2 trials, n = 108) : **−9.23 (–16.02 to –2.43)** Long term (12 months) (3 trials, n = 301): −4.94 (–10.45 to 0.58) Disability, weighted mean difference (95% CI) Post-treatment (3 trials, n = 188): **−12.35 (–23.00 to –1.69)** Intermediate (2 trials, n = 267): **−5.23 (–9.54 to –1.32)** Long term (12 months) (3 trials, n = 301): −3.17 (–15.96 to –0.38) A vs. D Pain intensity, weighted mean difference (95% CI) Post-treatment (1 trial, n = NR): NS (no data reported) Short-term (3 months) (3 trials, n = 200) : −7.63 (–17.20 to 1.93) Intermediate (6 months) (2 trials, n = 141): −5.58 (–16.65 to 5.48) Long-term (1 trial, n = 346): NS (no data reported) Disability, weighted mean difference (95% CI) Post-treatment (2 trials, n = 139): **−11.20 (–16.78 to –5.62)** Short-term (3 months) (3 trials, n = 200) : −2.55 (–10.07 to 4.97) Intermediate (6 months) (3 trials, n = 241): −4.42 (–9.90 to 1.05) Long-term (1 trial, n = 346): NS (no data reported)	NR	Fair

Appendix E19. Data Abstraction of Systematic Reviews of Exercise

Author, Year	Methods for Synthesizing Results of Primary Studies	Results	Adverse Events	Quality
van Middelkoop 2010 (cont.)		A vs. E (no pooling due to heterogeneity) Aerobic exercise training vs. lumbar flexion exercise program of 3 months (1 study) Pain intensity 3 months: statistically significant difference between groups (no data reported) General exercise program (strengthening and stretching) versus motor control exercise program (improving function of specific trunk muscles) of 12 weeks (1 study) Function 8 weeks: **mean adjusted between-group difference, 2.9 (favoring motor control exercise)** 6 and 12 months: "similar group outcomes" (no data reported) Global perceived effect 8 weeks: **mean adjusted between-group difference, 1.7 (favoring motor control exercise)** 6 and 12 months: "similar group outcomes" (no data reported) Yoga program vs. conventional exercise class program of 12 weeks (1 study) Back-related function 12 weeks: "superior in the yoga group" (no data reported) Various exercise interventions (9 studies) - no statistical differences		

Appendix E19. Data Abstraction of Systematic Reviews of Exercise

Author, Year	Comparison	Data Sources	Number and Type of Studies	Interventions and Number of Patients	Methods for Rating Methodological Quality of Primary Studies
Oesch 2010	1) Exercise vs usual care	August 2008: MEDLINE, EMBASE, PEDro, Cochrane Library databases, NIOSHTIC-2, and PsycINFO; English only	23 RCTs (n = 4138) (20 with data for meta-analysis, 17 comparisons of exercise vs. usual care and 11 comparisons of two different exercise) nonacute nonspecific LBP, duration ≥ weeks	1) A: Exercise versus B: usual care	criteria according to Juni et al.

Appendix E19. Data Abstraction of Systematic Reviews of Exercise

Author, Year	Methods for Synthesizing Results of Primary Studies	Results	Adverse Events	Quality
Oesch 2010	Meta regression and random effects models (Stata); odds ratios (OR) calculated; heterogeneity assessed using I^2 statistic	A vs B Work Disability Short term (closest to 4 wks) (5 trials, 6 comparisons, n = 1030) OR = 0.80 (95% CI 0.51 to 1.25); addition of 1 low quality study: OR = 0.68 (95% CI, 0.42 to 1.10) Intermediate (closest to 6 wks) (4 trials, 5 comparisons, n = 971) OR = 0.78 (95% CI 0.45 to 1.34) Long term (closest to 12 months) (8 trials, 10 comparisons, n = 1992) **OR = 0.66 (95% CI 0.48 to 0.92); addition of 2 low quality studies, OR = 0.70 (95% CI 0.54 to 0.91) (favor exercise, reduced work disability)** Influence of exercise (output individually designed) characteristics, long term (8 trials, n = 1149 group A, n = 843 group B) **OR = 0.59 (95% CI 0.45 to 0.78)**; I^2 = 60.4%; none of variables below were significant in meta-regression -delivery type (home-based exercises vs supervised exercises), -dose (high- vs low-dose exercise), -administration within a cognitive behavioral approach (yes/no), -work context (yes/no) Comparison of different exercise interventions (13 trials, 15 interventions) Effect of more contact hours: OR 1.07 (95% CI, 0.67 to 1.72) 3 trials applying exercise w/in behavioral approach: (OR 0.75, 95% CI 0.47 to 1.20) vs. trials without (OR 1.74, 95% CI 0.71 to 4.30) 1 trial on work-related exercise in inpatient (**OR 0.53, 95% CI 0.30 to 0.93)** compared with exercise not specifically designed to restore work-related physical capacity (OR 1.25, 95% CI 0.80 to 1.97)	NR	Fair

Please see Appendix C. Included Studies for full study references.

Appendix E20. Data Abstraction of Randomized Controlled Trials of Exercise

Author, Year	Country Number of Centers and Setting	Inclusion Criteria	Number Randomized, Analyzed Attrition	Intervention
Albaladejo 2010	Spain 8 centers Primary care	Presenting for LBP with no "red flags" for systemic disease or referral for surgery Excluded: bedridden, physiotherapy in previous 12 months, inflammatory rheumatologic disease, fibromyalgia	69 randomized 69 completed 0% attrition *Randomization of physicians who recruited subjects (i.e., cluster randomized)*	A. Education + 4 sessions of physiotherapy (n=100) B. Education (n=139) C. Usual care (n=109)
Albert, 2012	Denmark Single center Secondary care facility (after unsuccessful treatment in primary care)	18 to 65 years of age, radicular pain of dermatomal distribution to the knee or below in 1 or both legs, leg pain > 3 on a 1- to 10-point scale at first visit to the clinic, and duration of sciatica between 2 weeks and 1 year. EXCLUSION cauda equina syndrome, pending worker's litigation, previous back surgery, spinal tumors, pregnancy, a language other than Danish as their first language, or an inability to follow the rehabilitation protocol due to concomitant disease such as depression or heart failure.	Randomized, N = 181 Analyzed, N = 181 Attrition, 7.2% (13/181)	A: Symptom-guided exercises (n = 95). Directional end-range exercises and postural instructions guided by the individual patient's directional preference (based on the McKenzie method); stabilizing exercises for the transverse abdominis and multifidus muscles and dynamic exercises for the outer layers of the abdominal wall and back extensors; all patients received home exercise programs B: Sham exercises (n = 96). Optional exercises that were not back related but were low-dose exercises to simulate an increase in systemic blood circulation. Both groups received identical information and advice and optional paracetamol and/or NSAIDs. Treatment lasted for 8 weeks with a minimum of 4 and a maximum of 8 treatments. Patients were discouraged from receiving any additional treatment of their sciatica.

Appendix E20. Data Abstraction of Randomized Controlled Trials of Exercise

Author, Year	Study Participants	Duration of Pain (acute, subacute, chronic)	Outcome Measures	Duration of Followup
Albaladejo 2010	A vs. B vs. C Median age: 51 vs. 51 vs. 53 Female sex: 68% vs. 63% vs. 72% Race: NR Duration of pain >3 months: 72% vs. 78% vs. 89% Median pain intensity: 7.5 vs. 8 vs. 8 Median RMQ: 9.5 vs. 9.0 vs. 7.5 Median CSQ: 7.0 vs. 8.0 vs. 6.0 Median SF-12 PCS: 34.8 vs. 35.8 vs. 36.5 Median SF-12 MCS: 44.6 vs. 50.1 vs. 49.8	Chronic (79.8% with pain >3 months, n = 265)	VAS, RMQ, CSQ, SF-12	26 weeks
Albert, 2012	A vs. B Mean age (years): 46 vs. 44 Female: 43% vs. 53% Race NR Pain etiology NR Mean number of treatments: 5 vs. 5 Baseline Current leg pain (LBPRS): 4.3 ± 2.3 vs. 4.5 ± 2.5 Total leg pain, median (IQR): 18 (15–21) vs. 18 (12–21); p=NS Disability (RMDQ), median (IQR): 16 (11–18) vs. 15 (12–18) Quality of Life: 0.62 ± 0.18 vs. 0.62 ± 0.62	A vs. B 0–4 weeks: 25% vs. 18% 5–12 weeks: 59% vs. 63% 12–52 weeks: 16% vs. 19%	Low Back Pain Rating Scale (LBPRS), measures low back and leg pain on a 0 to 10 scale; current leg pain used as primary pain outcome; clinically important change in current leg pain was defined as a change of 2 points Total leg pain (LBPRS), composite score measured on a 30-point scale (a sum score of current leg pain, worst leg pain in the last 2 weeks, and average leg pain in the last 2 weeks) Roland Morris Disability Questionnaire (RMDQ), Danish version; clinically important change in activity limitation was defined as 30% or more change from baseline EuroQOL (EQ-5D), quality of life using adjusted Danish scores Global improvement, measured on a 5-point Likert scale Patient Satisfaction with Information (satisfied with information given and able to use all or most of it)	12 months

Appendix E20. Data Abstraction of Randomized Controlled Trials of Exercise

Author, Year	Results	Adverse Events Including Withdrawals	Funding Source	Quality Rating	Comments
Albaladejo 2010	A vs. B vs. C Change in median VAS, low back pain: -2.0 vs. -2.0 vs. 0 Change in median VAS, referred pain: -2.0 vs. -2.0 vs. -0.5 Improvement in RMQ: 2.0 vs. 1.6 vs. -0.3 Change in CSQ: -1.0 vs. -1.0 vs. 2.0 Change in SF-12 PCS: -3.2 vs. -2.4 vs. 0.6 Change in SF-12 MCS: -2.8 vs. -1.8 vs. 6.1	NR	"Foundation and other funds were received"	Fair	Also self-reported satisfaction and interim time-point results; Results reporting is poor; not describe between group comparisons' stat tests
Albert, 2012	A vs. B Current leg pain (LBPRS) (mean, SD) 8 weeks (end of treatment): 1.5 ± 2.1 vs. 2.3 ± 2.7; p=0.06 EPC calc of test mean diff -0.8 (95% CI -0.09 to -1.15) 12 months: 1.5 ± 2.1 vs. 1.4 ± 2.4; p=NS Total leg pain (LBPRS) (median, IQR) 8 weeks: 4 (0–9) vs. 4 (0–12); p=NS 12 months: 3 (0–10) vs. 2 (0–8); p=NS Disability (RMDQ) (median, IQR) 8 weeks: 6 (2–12) vs. 6 (2–12); p=NS 12 months: 3.5 (1–10) vs. 3.5 (1–10); p=NS ≥30% improvement from baseline: 73% vs. 77.5%; p=NS Quality of Life (EQ-5D (mean, SD) 12 months: 0.82 ± 0.21 vs. 0.79 ± 0.24; p=NS Global improvement 8 weeks Much better: 80% vs. 60% Some better: 14% vs. 26% 12 months: Much better: 84% vs. 76% Some better: 16% vs.18% Group A significantly (p<0.008) more improved (better or much better) compared with group B at both time points Patient satisfaction: 93.5% vs. 90.5%; p=NS	NR	Federal, institutional, and foundation funds		Global improvement estimated from figure 3 of article Do we care about nerve root compression signs and sick leave? They also report these outcomes

Appendix E20. Data Abstraction of Randomized Controlled Trials of Exercise

Author, Year	Country Number of Centers and Setting	Inclusion Criteria	Number Randomized, Analyzed Attrition	Intervention
Bronfort 2011	United States Single center University research clinic	Age 18-65 years, primary complaint of mechanical LBP ≥6 weeks w/w/o radiating pain to the lower extremity Excluded: previous lumbar surgery, vascular disease, pain score <3	301 randomized 245 completed 19% attrition	A. Supervised exercise therapy for 12 weeks (n=100) B. Chiropractic spinal manipulation for 12 weeks (n=100) C. Home exercise and advice for 12 weeks (n=101)
George, 2008B	United States Multicenter (3) Outpatient clinics	Age 15 to 60 years, ability to read and speak English, QTFSD classification 1a or 1b (acute or sub acute LBP without radiation below the gluteal fold) or 2a or 2b (acute or sub-acute LBP with proximal radiation to the knee) or 3a or 3b (acute or sub-acute LBP with distal radiation below the knee). EXCLUSION any other QTFSD classification; pregnancy; osteoporosis	N = 108 Analyzed, N = 102 Attrition, 29.4% (30/102)	A: TBC + Graded Exposure (GX) (n = 33). Fearful activities assessed; top 2 most feared activities implemented under this protocol using progression based on NRS fear rating and performed under supervision of PT and clinical staff. Also received patient education materials focused on biopsychosocial model. B: TBC + Graded Activity (GA) (n = 35). Parameters (duration, intensity, and frequency) used to reach pain tolerance were then established as the activity quota; graded activity principles were used to progress exercise during subsequent treatment sessions. Also received patient education materials focused on biopsychosocial model C: Physical therapy based on the treatment-based classification (TBC) system (Delitto et al.) (n = 34). Also received educational materials that were anatomically focused.

Appendix E20. Data Abstraction of Randomized Controlled Trials of Exercise

Author, Year	Study Participants	Duration of Pain (acute, subacute, chronic)	Outcome Measures	Duration of Followup
Bronfort 2011	A vs. B vs. C Mean age: 44.5 vs. 45.2 vs. 45.6 years Female sex: 57% vs. 66% vs. 58% Race: NR Duration of back pain: 4.8 vs. 5.0 vs. 5.0 years Mean pain severity score (0-10): 5.1 vs. 5.4 vs. 5.2 Roland-Morris disability score (0-23): 8.4 vs. 8.7 vs. 8.7	Chronic; median duration 4.8 to 5 (0-51) years	Self-reported questionnaire assessing pain, disability, and quality of life; lumbar range of motion; strength; and endurance	52 weeks
George, 2008B	A vs. B vs. C Mean age (years): 40.1 vs. 37.6 vs. 34.9 Female: 64% vs. 69% vs. 68% Race NR Pain etiology NR Prior history of LBP: 67% vs. 69% vs. 50% Referred leg pain: 42% vs. 49% vs. 38% Baseline Pain (NRS): 4.7 ± 2.1 vs. 5.2 ± 1.8 vs. 4.3 ± 2.0 Function (PIS): 3.1 ± 1.6 vs. 3.6 ± 2.1 vs. 2.9 ± 1.7 Disability (ODI): 30.7 ± 15.6 vs. 31.1 ± 15.8 vs. 29.2 ± 15.7	Acute and sub-acute; operationally defined as reporting current symptoms for 1–24 weeks A vs. B vs. C duration of current LBP episode (weeks): 9.8 vs. 5.8 vs. 6.7; p=0.015	Numerical Rating Scale (NRS), pain intensity (0-10 cm), higher score = greater pain; patients rated pain intensity over 3 conditions, the present pain intensity, the worst pain intensity over the past 24 h, and the best pain intensity over the past 24 h. These 3 ratings were summed and divided by 3 (arithmetic mean) for use in data analyses. Oswestry Disability Index (ODI), self-reported disability regarding how LBP affects ADLs (0-100 with higher score = more disability). Physical Impairment Scale (PIS), assessed by PT, score range 0–7, and higher scores indicate higher levels of physical impairment	6 months

Appendix E20. Data Abstraction of Randomized Controlled Trials of Exercise

Author, Year	Results	Adverse Events Including Withdrawals	Funding Source	Quality Rating	Comments
Bronfort 2011	Only significant between-group differences in patient-reported outcomes were for satisfaction (favoring A, p<0.01 at 12 weeks and p<0.001 at 52 weeks) Overall treatment effect was significant for endurance (p<0.05) and strength (p<0.05) but not range of motion (also favoring A).	A vs. B vs. C Nonserious adverse events: 1% (1/100) vs. 1% (1/100) vs. 4% (4/101) All adverse events were transient, required little to no change in activity level, and were considered non-serious	NR	Good	Large tables of data at each time point available
George, 2008B	A vs. B vs. C Pain intensity (NRS, 0–10) **High fear** Baseline: 5.1 ± 2.1 vs. 5.1 ± 1.9 vs. 5.1 ± 1.8 4 weeks: 2.1 ± 2.0 vs. 2.3 ± 2.1 vs. 2.0 ± 1.6 6 months: 2.1 ± 2.3 vs. 1.5 ± 2.1 vs.1.6 ± 1.3 **Low fear** Baseline: 3.9 ± 1.5 vs. 4.9 ± 2.1 vs. 3.1 ± 2.1 4 weeks: 1.7 ± 0.9 vs. 2.1 ± 2.1 vs. 1.8 ± 1.9 6 months: 1.0 ± 1.0 vs. 2.3 ± 1.7 vs. 1.0 ± 1.2 Disability (ODI, 0–100) **High fear** Baseline: 32.3 ± 16.3 vs. 29.9 ± 18.4 vs. 32.9 ± 16.1 4 weeks: 16.5 ± 12.1 vs. 11.5 ± 11.8 vs.16.4 ± 14.9 6 months: 16.7 ± 17.6 vs. 11.3 ± 14.2 vs.11.4 ± 11.5 **Low fear** Baseline: 20.4 ± 13.1 vs. 30.4 ± 13.3 vs. 23.0 ± 15.5 4 weeks: 11.4 ± 11.6 vs. 16.7 ± 11.9 vs. 12.0 ± 11.5 6 months: 9.7 ± 8.2 vs. 15.8 ± 11.1 vs. 5.8 ± 7.1 p=NS for all comparisons	No adverse events reported during followup	NIH-NIAMS Grant AR051128		

Appendix E20. Data Abstraction of Randomized Controlled Trials of Exercise

Author, Year	Country Number of Centers and Setting	**Inclusion Criteria**	Number Randomized, Analyzed Attrition	Intervention
George, 20088 (cont.)				

Appendix E20. Data Abstraction of Randomized Controlled Trials of Exercise

Author, Year	Study Participants	Duration of Pain (acute, subacute, chronic)	**Outcome Measures**	Duration of Followup
George, 20088 (cont.)				

Appendix E20. Data Abstraction of Randomized Controlled Trials of Exercise

Author, Year	Results	Adverse Events Including Withdrawals	Funding Source	Quality Rating	Comments
George, 2008B (cont.)	Effect sizes Pain intensity (NRS, 0-10) 4 weeks A vs. B: 0.11 A vs. C: –0.05 B vs. C: –0.16 6 months A vs. B: –0.32 A vs. C: –0.26 B vs. C: 0.01 Disability (ODI, 0-100) 4 weeks A vs. B: –0.40 A vs. C: –0.02 B vs. C: 0.39 6 months A vs. B: –0.38 A vs. C: –0.37 B vs. C: 0.01 p=NS for all comparisons. These post hoc effect sizes suggest that for the primary comparisons of interest (GX vs. GA and GX vs. TBC) total sample sizes needed to detect these magnitudes of differences would range from 114 to over 700. Proportion of Success vs. Failure (ODI >10 point change, NRS >2 point change) at 6 months NRS 46% vs. 43% vs 41% ODI 43%41%, 56% p = 0.70				

Appendix E20. Data Abstraction of Randomized Controlled Trials of Exercise

Author, Year	Country Number of Centers and Setting	Inclusion Criteria	Number Randomized, Analyzed Attrition	Intervention
Hagen, 2010	Norway Single center Outpatient spine clinic	Age 18–60 years; sick listed (i.e., sick leave from work) for 8–12 weeks for LBP w/w/o sciatica EXCLUSION on sick leave >12 weeks, not sick listed, pregnancy, recent low back trauma, cauda equina symptoms, cancer, osteoporosis, rheumatic low back disease, ongoing treatment for LBP by another specialist, and information from the general practitioner on the sickness certificates indicating forthcoming return to work.	Randomized, N = 246 Analyzed, N = 246 Attrition, 3.3% (8/246)	A: Standardized physical exercise program (n = 124). Aim was to re-educate the trunk muscle to its normal stabilizing role and to improve balance, muscle coordination, and proprioception; program included warm-up (8 minutes), circuit training (34 minutes), stretching (13 minutes), and relaxation (5 minutes); duration 1 hour, 3x/week for 8 weeks. B: No treatment (n = 122). Received a brief intervention program before randomization.

Appendix E20. Data Abstraction of Randomized Controlled Trials of Exercise

Author, Year	Study Participants	Duration of Pain (acute, subacute, chronic)	Outcome Measures	Duration of Followup
Hagen, 2010	A vs. B Mean age (years): 40.7 vs. 41.6 Female: 52% vs. 50% Race NR Pain etiology NR Previous sick leave for LBP: 72% vs. 75%	Unclear	Pain intensity on a scale from 1 to 10 scale; Physical function (sock test, pick-up test, loaded reach test, 15 meter walk, fingertip-to-floor test, static balance test) Reported walking distance; Self-reported physical activity, determined by measuring the type and frequency of physical activity, defined as regular participation for at least 30 minutes each time and at an intensity high enough to produce sweat (1 year prior to sick leave and in past 2 months); Roland Morris Disability Questionnaire (RMDQ), higher score = reduced function; Hopkin's Symptom Check list (HSCL-25), measure of psychological distress; Subjective Health Complaint Inventory (SHCI), somatic and psychological complaints experienced during the last 30 days were measured; Return to work	24 months

Appendix E20. Data Abstraction of Randomized Controlled Trials of Exercise

Author, Year	Results	Adverse Events Including Withdrawals	Funding Source	Quality Rating	Comments
Hagen, 2010	Only statistically significant difference found was for the sock test (physical function), which was more improved in Group A vs. B: mean difference –0.34; 95% CI, –0.66 to –0.01; p=0.041 (time point NR). No statistically significant difference between groups at any followup time point - 6, 12, 18 or 24 months - for the following (no data provided): Pain intensity Functional tests (pick-up test, loaded reach test, 15 meter walk, fingertip-to-floor test, static balance test) Physical activity Walking distance Disability (RMDQ) Subjective health complaints Psychological distress (HSCL-25) Return to work	NR	EXTRA funds from the Norwegian Foundation for Health and Rehabilitation, Grant No. Nkr 840 000 (Euro 105 000)		Percentage of patients that returned to work and self-reported physical activity are presented in Figures 2 and 3. Is it worth estimating from the graphs? Both groups increased return to work, reported less pain and better function, and reduced fear-avoidance beliefs for physical activity during the followup period; authors provide change score for all patients which I did not extract assuming it is not relevant/helpful

Appendix E20. Data Abstraction of Randomized Controlled Trials of Exercise

Author, Year	Country Number of Centers and Setting	Inclusion Criteria	Number Randomized, Analyzed Attrition	Intervention
Hartvigsen 2010	Denmark Single center Outpatient back pain clinic	LBP with or without leg pain >8 weeks, average pain score >3 (on 11-point NRS) during previous 2 weeks, and had completed 4 weeks of previous treatment Excluded: unable to sit on a stationary bike for at least 30 minutes, other comorbidities preventing full participation	136 randomized 126 completed 7% attrition	A. Supervised Nordic walking in groups twice/week for 8 weeks (n=45) B. Nordic walking instruction for 1 hour, with instruction to continue independently (n=46) C. Active living and exercise information (n=45)

Appendix E20. Data Abstraction of Randomized Controlled Trials of Exercise

Author, Year	Study Participants	Duration of Pain (acute, subacute, chronic)	Outcome Measures	Duration of Followup
Hartvigsen 2010	A vs. B vs. C Mean age: 49.2 vs. 45.4 vs. 45.5 years Female sex: 76% vs. 69% vs. 68% Race: NR LBP rating scale (0-100), pain: 46.1 vs. 50.7 vs. 47.3 LBP rating scale (0-100), function: 44.4 vs. 47.3 vs. 48.9 Patient-specific function scale (0-100): 18.4 vs. 20.1 vs. 17.3 EQ-5D (0-100): 67.5 vs. 62.7 vs. 63.9	Subacute/chronic: >8 weeks (mean duration NR)	LBP rating scale, patient-specific function scale, EQ-5D	52 weeks

Appendix E20. Data Abstraction of Randomized Controlled Trials of Exercise

Author, Year	Results	Adverse Events Including Withdrawals	Funding Source	Quality Rating	Comments
Hartvigsen 2010	A vs. B vs. C Mean improvement at 8 weeks in LBP rating scale, pain: 8.8 vs. 3.4 vs. 4.8; significant at all time points for group A, significant only at 8 and 26 weeks for group B, significant only at 8 weeks for group C; no significant between-group differences at any point Mean improvement at 8 weeks in LBP rating scale, function: 7.4 vs. 3.2 vs. 3.8; significant at all time points for group A, never significant for group B, and significant only at 8 and 26 weeks in group C; no significant between-group differences at any point Patient-specific function scale: all groups improved significantly from baseline, but there were no between-group differences EQ-5D: very small and similar changes in all groups	NR	NR	Fair	Most data reported in figures

Appendix E20. Data Abstraction of Randomized Controlled Trials of Exercise

Author, Year	Country Number of Centers and Setting	Inclusion Criteria	Number Randomized, Analyzed Attrition	Intervention
Helmhout, 2008	Netherlands Muticenter (6) PT dept in military primary care clinics	military employees of the Dutch army, age 18-54 years, ≥4 weeks of continuous or recurrent (at least 3 times a week) episodes of LBP, pain localized between posterior iliac crests and angulus inferior scapulae, with or without radiation in the legs, availability in duty time to visit the local military health center 2 times a week during 10 consecutive weeks, with no more than 2 sessions of absence because of job-related activities (e.g., military exercise, course, leave), and willingness to abandon other treatment interventions for the lower back during the intervention period. EXCLUSION spinal surgery in the last 2 years; specific treatment for LBP in the last 4 weeks (e.g., PT, manual therapy); severe LBP that hindered performing maximal isometric strength efforts; and specific LBP, defined as herniated disk,	Randomized, N = 127 Analyzed, N = 127 Attrition, 15.7% (20/127)	A: Lumbar extensor strength training program (n = 71). Standardized, progressive resistance training of the isolated lumbar extensor muscle groups aimed at both strength and endurance gain; duration 10 weeks, 14 sessions 2x/wk and 3 isometric back strength tests (in weeks 1, 5, and 10). Training sessions were carried out on a Total Trunk Rehab machine. Patients were not allowed to undergo cotreatments during the treatment period. B: Regular PT program (n = 56). Regular PT for 10 weeks, or less when the patient was free of complaints; could include hands-on treatment (e.g., passive mobilizing and pain cushioning techniques, manual therapy) and/or hands-off treatment (e.g., exercise therapy, individual education, instruction on the back function) (in the Dutch army, active therapy forms are favored); no cotreatments allowed, nor exercise on equipment that mimicked the specific components of the lower back machine .

Appendix E20. Data Abstraction of Randomized Controlled Trials of Exercise

Author, Year	Study Participants	Duration of Pain (acute, subacute, chronic)	Outcome Measures	Duration of Followup
Helmhout, 2008	A vs. B Mean age (years): 37 vs. 35 Female: 3% vs. 4% Race NR Pain etiology NR Prior LBP complaints: 76% vs. 74% Pain radiating to legs: 10% vs. 10% Work absenteeism in last year due to LBP: 10% vs. 8% Baseline Function (PSFS): 178 ± 65 vs. 178 ± 52 Disability (RMDQ): 8.3 ± 4.8 vs. 7.9 ± 4.4 Back extension strength (NMT): 214 ± 64 vs. 212 ± 65	A vs. B <4 weeks: 0% vs. 2% 4–6 weeks: 8% vs. 16% 6–12 weeks: 20% vs. 27% 3–6 months: 20% vs. 9% 6–12 months: 15% vs. 7% ≥12 months: 36% vs. 39%	Patient-Specific Functional Scale (PSFS, score 0–300), patients selected at baseline the 3 most important ADLs that were hampered by their LBP, and rated them on a 100-mm visual analog scale at each test moment (high score indicates greater disability); Roland-Morris Disability Questionnaire (RMDQ, score 0–24), disability (high score indicates greater disability); Global perceived effect (GPE), self-assessment on a 7-point scale (1 completely recovered, 2 much improved, 3 slightly improved, 4 no change, 5 slightly worsened, 6 much worsened, 7 vastly worsened); Self-Reported Back Pain Evaluation, questions about back pain episodes, back treatment, medication, and work absenteeism; Patient satisfaction (“How satisfied are you now about the treatment that was given to you?”); Isometric (net) muscular torque (NMT) of the lumbar extensors. mean of 3 positions	62 weeks

Appendix E20. Data Abstraction of Randomized Controlled Trials of Exercise

Author, Year	Results	Adverse Events Including Withdrawals	Funding Source	Quality Rating	Comments
Helmhout, 2008	A vs. B (mean ± SD; between group difference, 95% CI) Function (PSFS, score 0–300) 5 weeks: 119 ± 70 (n = 64) vs. 116 ± 67 (n = 46) 10 weeks: 85 ± 72 (n = 59) vs. 97 ± 74 (n = 47); –0.608 (–2.693 to 1.477), p=0.57 36 weeks: 74 ± 72 (n = 57) vs. 64 ± 59 (n = 37) 62 weeks: 69 ± 71 (n = 61) vs. 65 ± 69 (n = 45); –0.136 (–0.344 to 0.616), p=0.58 Disability (RMDQ, score 0–24) 5 weeks: 5.8 ± 4.8 (n = 64) vs. 4.2 ± 4.2 (n = 46) 10 weeks: 3.4 ± 4.6 (n = 59) vs. 3.5 ± 4.2 (n = 47); –0.025 (–0.134 to 0.085), p=0.66 36 weeks: 3.2 ± 4.3 (n = 57) vs. 2.7 ± 3.8 (n = 37) 62 weeks: 2.6 ± 4.4 (n = 61) vs. 2.5 ± 3.9 (n = 45); 0.000 (– 0.025 to 0.026), p=0.99 Global perceived effect (GPE) 5 weeks: no data 10 weeks: 2.4 ± 0.8 (n = 59) vs. 2.4 ± 0.7 (n = 47) 36 weeks: 2.5 ± 1.0 (n = 57) vs. 2.3 ± 0.9 (n = 37) 62 weeks: 2.2 ± 1.0 (n = 61) vs. 2.3 ± 1.0 (n = 45); –0.002 (–0.010 to 0.006), p=0.66 LBP episodes 6 months (back pain in 1st half of year after the end of the treatment period?) (A, n = 56; B, n = 40): No, not at all: 9% vs. 18% Yes, incidentally: 57% vs. 63% Yes, monthly: 11% vs. 3% Yes, weekly: 23% vs. 18% 12 months (back pain in 2nd half of year after the end of the treatment period?) (A, n = 61; B, n = 46): No, not at all: 25% vs. 22% Yes, incidentally: 55% vs. 50% Yes, monthly: 2% vs. 11% Yes, weekly: 18% vs. 17%	A vs. B 1.4% (1/71; acute lumbago) vs. 0% (0/56)	NR		

Appendix E20. Data Abstraction of Randomized Controlled Trials of Exercise

Author, Year	Country Number of Centers and Setting	Inclusion Criteria	Number Randomized, Analyzed Attrition	Intervention
Helmhout, 2008 (cont.)				
Henchoz 2010	Switzerland Single center Spine unit	Age 18-60 years, subacute or chronic LBP, phases 2-6 of Krause classification, without neurologic deficit Excluded: phases 7-8 of Krause classification, total disability pension, sciatica, pregnancy, acute rheumatic disease, spinal fracture in previous 3 months, osteoporosis, tumor, heart or respiratory failure, drug addiction, psychiatric pathology	105 randomized 91 completed 13% attrition	A. Functional multidisciplinary rehabilitation, followed by a 12-week exercise program (n=56) B. Functional multidisciplinary rehabilitation, followed by usual care (n=49)

Appendix E20. Data Abstraction of Randomized Controlled Trials of Exercise

Author, Year	Study Participants	Duration of Pain (acute, subacute, chronic)	Outcome Measures	Duration of Followup
Helmhout, 2008 (cont.)				
Henchoz 2010	A vs. B Mean age: 41 vs. 39 years Female sex: 34% vs. 45% Race: NR Mean VAS: 5.3 vs. 5.1	Subacute/chronic (mean duration NR)	VAS, ODI, SFS, endurance, and range of motion	52 weeks

Appendix E20. Data Abstraction of Randomized Controlled Trials of Exercise

Author, Year	Results	Adverse Events Including Withdrawals	Funding Source	Quality Rating	Comments
Helmhout, 2008 (cont.)	Patient satisfaction (very satisfied; final degree of satisfaction at end of treatment program): 89% (n = 56) vs. 89% (n = 46) Back extension strength (NMT) 5 weeks: 23 ± 62 (n = 64) vs. 246 ± 74 (n = 46) 10 weeks: 244 ± 66 (n = 59) vs. 247 ± 73 (n = 47) 36 weeks: 264 ± 64 (n = 57) vs. 254± 73 (n = 37) 62 weeks: 267 ± 62 (n = 61) vs. 249 ± 74 (n = 45) p=NS for all timepoints				Typo in table re 5 week NMT for Group A (243?, 23X?)
Henchoz 2010	A vs. B, end of functional multidisciplinary rehabilitation- 1 year ODI: 30.2-25.3 (p<0.001) vs. 30.5-27.2 (p=0.059) VAS: 3.8-3.8 (p=0.521) vs. 3.6-3.8 (p=0.995) SFS: 66.1-89.8 (p<0.05) vs. 65.5-78.8 (p=0.653) Sorensen test (s): 64.8-81.6 (p<0.05) vs. 67.1-63.9 (p=0.249) MMS test, flexion (cm): 5.65-5.15 (p=0.368) vs. 5.27-5.19 (p=0.561) MMS test, extension (cm): -1.63 to -1.61 (p=0.138) vs. -1.46 to -1.64 (p=0.353) Fingertip-floor distance (cm): 126.5-135.7 (p=0.076) vs. 129.1-136.0 (p=0.470) Shirado test (s): 11.3-8.0 (p=0.063) vs. 17.3-10.0 (p<0.001) Modified Bruce test (min): 11.2-8.4 (p<0.001) vs. 11.2-8.7 (p<0.001)	NR	None	Fair	

Appendix E20. Data Abstraction of Randomized Controlled Trials of Exercise

Author, Year	Country Number of Centers and Setting	Inclusion Criteria	Number Randomized, Analyzed Attrition	Intervention
Hofstee, 2002	Netherlands Single center Outpatient clinic	Age < 60 years, radicular pain <1 month's duration, available for 6 months of followup, and able to provide informed consent EXCLUSION cauda equina syndrome or severe weakness (Medical Research Council grade <3), previous bed rest or physiotherapy, or unwilling to comply with one of the three treatment strategies	Randomized, N = 250 Analyzed, N = 250 Attrition, 10% (25/250)	A: Physiotherapy (n = 83). The protocol consisted of instructions and advice, segmental mobilization, disc unloading and loading exercises, depending on patients' conditions, and hydrotherapy; 2x/week for at least 4 to, at most, 8 weeks; asked to perform daily exercises at home. B: Bed rest (at home or in-hospital) (n = 84). Instructed to stay in bed for 7 days; only allowed out of bed to use the bathroom and shower. After this period, patients supposed to rest as much as possible when in pain. C: Continuation of ADLs (control group) (n = 83). Continue jobs, household activities, studies, or hobbies to the best of the patients' abilities; advised to adjust the intensity, duration, and frequency of their activities according to the pain they experienced. All patients received a brochure with instructions and advice regarding their respective treatment; were allowed to use analgesic medication and to call the investigator for help if they had problems or questions. When patients called, they were reassured and urged to comply with their assigned treatment; if necessary, they were seen at the outpatient clinic.

Appendix E20. Data Abstraction of Randomized Controlled Trials of Exercise

Author, Year	Study Participants	Duration of Pain (acute, subacute, chronic)	Outcome Measures	Duration of Followup
Hofstee, 2002	A vs. B vs. C Mean age (years): 38 vs. 38 vs. 41.9; p=0.02 Female: 37% vs. 32% vs. 31% Race NR Pain etiology NR Previous LBP: 70% vs. 70% vs. 65% Previous sciatica: 32% vs. 34% vs. 25% Past lumbar surgery: 5% vs. 3% vs. 2% Root compression on CT: 60% vs. 63% vs. 58% Baseline Pain (VAS, 0-100): 60.9 ± 20.1 vs. 65.5 ± 18.5 vs. 60.7 ± 21.4 Disability (QDS): 56.0 ± 17.6 vs. 58.6 ± 14.6 vs. 57.4 ± 16.3	Mixed acute/subacute (radicular pain < 1 month)	Visual analog scale (VAS) for pain (100 cm), range 0 (no radicular pain) to 100 (max pain); Quebec Disability Scale (QDS), measures disturbance in ADLs (total score range, 0–100); 20 items, score for each item ranges from 0 (not difficult at all) to 5 (unable to do); Treatment failure (<2 months: severe intolerable pain and insistence on surgery, >2 months: pain resolution insufficient and patient willing to undergo surgery); Need for surgery (a cauda equina syndrome, acute severe weakness [Medical Research Council grade <3], or treatment failure and nerve root compression on CT, MRI or myelography)	6 months

Appendix E20. Data Abstraction of Randomized Controlled Trials of Exercise

Author, Year	Results	Adverse Events Including Withdrawals	Funding Source	Quality Rating	Comments
Hofstee, 2002	Mean improvement in scores from baseline, A vs. B, vs. C Pain (VAS, 0–100) 1 month (mean): 24.2 (n = 80) vs. 25.9 (n = 84) vs. 23.4 (n = 83) 1 month differences (95% CI) A vs. B: –1.7 (NR) A vs. C: 0.8 (–8.2 to 9.8) 2 months (mean): 37.0 (n = 77) vs. 38.1 (n = 82) vs. 37.3 (n = 79) 2 months difference (95% CI) A vs. B: –1.1 (NR) A vs. C: –0.3 (–9.4 to 10.0) 6 months (mean): 46.8 (n = 72) vs. 48.2 (n = 78) vs. 47.8 (n = 75) 6 months difference (95% CI) A vs. B: –1.4 (NR) A vs. C: –1.0 (–10.0 to 8.0) Disability (QDS, 0–100) 1 month (mean): 15.7 (n = 80) vs. 11.4 (n = 84) vs. 16.2 (n = 83) 1 month differences (95% CI) A vs. B: 4.3 (NR) A vs. C: –0.5 (–6.3 to 5.3) 2 months (mean): 26.3 (n = 77) vs. 23.5 (n = 82) vs. 26.3 (n = 79) 2 months difference (95% CI) A vs. B: 2.8 (NR) A vs. C: 0.0 (–7.2 to 7.3) 6 months (mean): 34.6 (n = 72) vs. 32.7 (n = 78) vs. 35.4 (n = 75) 6 months difference (95% CI) A vs. B: 1.9 (NR) A vs. C: –0.7 (–8.4 to 6.9)	New sciatica, 4% (10/250) Cauda equina syndrome, 0.4% (1/250) Pulmonary embolism, 0.4% (1/250) (this patient was in group B; 1.2% (1/84))	Hoelen Foundation		Confidence intervals could not be calculated for the difference b/w A vs. B at any timepoint because no SDs were provided. Unclear if the cauda equina syndrome was also in a patient from group B (bed rest)

Appendix E20. Data Abstraction of Randomized Controlled Trials of Exercise

Author, Year	Country Number of Centers and Setting	Inclusion Criteria	Number Randomized, Analyzed Attrition	Intervention
Hofstee, 2002 (cont.)				
Hurley 2015	Ireland 5 centers Acute public teaching hospital	Age 18-65 years, nonspecific LBP ≥3 months or ≥3 episodes in previous 12 months, no recent spinal injury, and low to moderate levels of physical activity Excluded: received treatment for LBP in previous 3 months, radicular pain indicative of nerve root compression, systemic inflammatory disease, severe spinal stenosis, fibromyalgia, neurological disorders, cancer, or acute or subacute LBP with <3 episodes in previous 12 months	246 randomized 110 completed 28% attrition	A. Exercise class for 8 weeks (n=83) B. Walking program for 8 weeks (n=82) C. Usual physiotherapy for 8 weeks (n=81)

Appendix E20. Data Abstraction of Randomized Controlled Trials of Exercise

Author, Year	Study Participants	Duration of Pain (acute, subacute, chronic)	Outcome Measures	Duration of Followup
Hofstee, 2002 (cont.)				
Hurley 2015	A vs. B vs. C Mean age: 45.8 vs. 46.2 vs. 44.2 years Female sex: 71% vs. 71% vs. 62% Race: NR Duration of LBP: 7.0 vs. 8.7 vs. 7.5 years Mean pain over past week, NRS: 5.6 vs. 5.5 vs. 6.0 ODI: 38 vs. 35 vs. 33 EQ-5D: 0.52 vs. 0.57 vs. 0.51 Low physical activity: 44% vs. 62% vs. 58% Moderate physical activity: 39% vs. 33% vs. 30%	Chronic: mean duration 7.0-8.7 years	Pain NRS, EQ-5D, ODI, IPAQ, other self-reported belief questionnaires	52 weeks

Appendix E20. Data Abstraction of Randomized Controlled Trials of Exercise

Author, Year	Results	Adverse Events Including Withdrawals	Funding Source	Quality Rating	Comments
Hofstee, 2002 (cont.)	Cumulative No. of patients, A vs. B vs. C; OR (95% CI) Treatment failure 1 month: 2% (n = 2) vs. 6% (n = 5) vs. 7% (n = 6); A vs. C: 0.3 (0.1–1.6); A vs. B: NR 2 months: 13% (n = 11) vs. 19% (n = 16) vs. 12% (n = 10); A vs. C: 1.1 (0.7–2.8); A vs. B: NR 6 months: 23% (n = 19) vs. 25% (n = 21) vs. 17% (n = 14); A vs. C: 1.5 (0.7–3.2); A vs. B: NR Surgery 1 month: 2% (n = 2) vs. 5% (n = 4) vs. 6% (n = 5); A vs. C: 0.4 (0.1–2.0); A vs. B: NR 2 months: 12% (n = 10) vs. 13% (n = 11) vs. 11% (n = 9); A vs. C: 1.1 (0.4–2.9); A vs. B: NR 6 months: 16% (n = 13) vs. 19% (n = 16) vs. 13% (n = 11); A vs. C: 1.2 (0.5–2.9); A vs. B: NR				
Hurley 2015	A vs. B vs. C ODI: 27 vs. 27 vs. 27; p=0.37 Average pain, NRS: 5.1 vs. 4.2 vs. 4.1; p=0.15 EQ-5D: 0.62 vs. 0.63 vs. 0.62; p=0.72	A vs. B vs. C Withdrawal due to adverse events: 0% vs. 8.5% (7/82) vs. 0%	Health Research Board Project Grant	Fair	Other belief scales available (all nonsignificant), as well as other time points

Appendix E20. Data Abstraction of Randomized Controlled Trials of Exercise

Author, Year	Country Number of Centers and Setting	Inclusion Criteria	Number Randomized, Analyzed Attrition	Intervention
Jensen 2012	Denmark Single center Outpatient back pain clinic	Age 18-60 years, persistent LBP with or without radiculopathy, pain ≥3 on 11-point NRS, duration of current symptoms 2-12 months, at least one modic change extending into the vertebral body, and previous unsuccessful primary care treatment	100 randomized 96 completed 4% attrition	A. Rest, avoiding hard physical activity and rest twice daily for one hour over 10 weeks (n=50) B. Exercise for 10 weeks (n=50)

Appendix E20. Data Abstraction of Randomized Controlled Trials of Exercise

Author, Year	Study Participants	Duration of Pain (acute, subacute, chronic)	Outcome Measures	Duration of Followup
Jensen 2012	A vs. B Mean age: 47 vs. 45 years Female sex: 67% vs. 69% Race: NR Mean pain, NRS: 5.6 vs. 5.1 Mean RMQ: 12.0 vs. 13.3 Mean EQ-5D: 0.68 vs. 0.62 Mean BDI: 10.7 vs. 9.6	Subacute/chronic ("persistent", duration of current symptoms 2-12 months, mean duration NR)	NRS, RMQ, EQ-5D, BDI	52 weeks

Appendix E20. Data Abstraction of Randomized Controlled Trials of Exercise

Author, Year	Results	Adverse Events Including Withdrawals	Funding Source	Quality Rating	Comments
Jensen 2012	A vs. B (adjusted differences for intervention group) Posttreatment Pain: 5.0 vs. 4.5; adjusted difference -0.07 (95% CI -0.9 to 0.7) RMQ: 11.0 vs. 11.1; adjusted difference -0.6 (95% CI -2.2 to 1.0) EQ-5D: 0.7 vs. 0.7; adjusted difference 0.04 (95% CI -0.007 to 0.09) BDI: 8.6 vs. 7.9; adjusted difference 0.67 (95% CI -0.99 to 2.3) vs. 0.08 (95% CI -0.3 to 0.4) One-year followup Pain: 4.8 vs. 4.3; adjusted difference -0.3 (95% CI -1.3 to 0.6) RMQ: 10.7 vs. 10.7; adjusted difference -1.2 (95% CI -3.3 to 1.0) EQ-5D: 0.7 vs. 0.7; adjusted difference 0.06 (95% CI -0.008 to 0.14) BDI: 9.5 vs. 8.0; adjusted difference -0.92 (95% CI -2.8 to 0.97) vs. -0.17 (95% CI -0.6 to 0.22)	No adverse events reported in any group	VELUX Foundation	Good	No differences in any outcome between groups

Appendix E20. Data Abstraction of Randomized Controlled Trials of Exercise

Author, Year	Country Number of Centers and Setting	Inclusion Criteria	Number Randomized, Analyzed Attrition	Intervention
Kell 2011	Alberta Community setting	Men and women aged 18 - 50 years old with chronic (≥3 months, ≥3 days per week) nonspecific (soft tissue in origin) low back (lumbar 1–5) pain (visual analogue scale [VAS] ≥3). Excluded: pain below the knee, spinal stenosis, herniated or ruptured disc(s), spondylolisthesis, infection in the lumbosacral area, tumor(s), scoliosis, rheumatologic disorder, osteoporosis, previous back surgery, usage of any prescriptive or nonprescriptive pain medication, history of metabolic, endocrine, cardiovascular, or neurological disease.	240 randomized 207 completed 13.75% attrition	A. Periodized musculoskeletal rehabilitation (PMR) training four days per week with 1,563 repetitions each week (n = 60) B. PMR training three days per week with 1,344 repetitions each week (n = 60) C. PMR training twice per week with 564 repetitions per week (n = 60) D. No training (n = 60)

Appendix E20. Data Abstraction of Randomized Controlled Trials of Exercise

Author, Year	Study Participants	Duration of Pain (acute, subacute, chronic)	Outcome Measures	Duration of Followup
Kell 2011	A vs B vs C vs D Mean age: 42.4 ± 5.6 vs 41.7 ± 6.1 vs 42.8 ± 6.3 vs 43.2 ± 5.9 Female sex: 30% vs 37% vs 33% vs 38.3% Race: NR Pain duration >3 months: 100% vs 100% vs 100% vs 100%	Chronic (100% with pain > 3 months)	VAS (pain), bench press (function), lat pull down (function), leg press (function), ODI (disability), PCS (QOL), MCS (QOL)	13 weeks

Appendix E20. Data Abstraction of Randomized Controlled Trials of Exercise

Author, Year	Results	Adverse Events Including Withdrawals	Funding Source	Quality Rating	Comments
Kell 2011	A vs B vs C vs D VAS pain: 4.35 ± 0.95 vs 4.77 ± 1.00 vs 4.96 ± 1.03 vs 5.70 ± 0.86 p≤0.05 difference A vs B, C, and D p≤0.05 difference B and C vs D Bench press (function): 79.3 ± 9.7 vs 70.4 ± 9.1 vs 68.2 ± 9.7 vs 53.3 ± 9.3 p≤0.05 difference A vs B, C, and D Lat pull down (function): 75.3 ± 7.1 vs 70.1 ± 7.7 vs 67.2 ± 7.4 vs 56.0 ± 6.1 p≤0.05 difference A vs B, C, and D p≤0.05 difference B and C Leg press (function): 237.2 ± 29.0 vs 201.7 ± 30.8 vs 184.2 ± 29.5 vs 139.9 ± 28.9 p≤0.05 difference A vs B, C, and D p≤0.05 difference B and C ODI: 27.1 ± 10.7 vs 31.6 ± 11.1 vs 31.8 ± 10.9 vs 39.1 ± 10.1 p≤0.05 difference A vs B, C, and D p≤0.05 difference B and C vs D PCS: 55.7 ± 7.8 vs 50.4 ± 8.0 vs 50.2 ± 8.7 vs 45.0 ± 8.0 p≤0.05 difference A vs B, C, and D p≤0.05 difference B and C vs D MCS: 57.7 ± 8.2 vs 52.6 ± 7.8 vs 53.1 ± 8.3 vs 46.0 ± 8.2 p≤0.05 difference A vs B, C, and D p≤0.05 difference B and C vs D	The authors report no occurrence of adverse events in treatment groups A and B. NR for treatment groups C and D.	The University of Alberta, Augustana Campus Research and Travel Grant.		

Appendix E20. Data Abstraction of Randomized Controlled Trials of Exercise

Author, Year	Country Number of Centers and Setting	Inclusion Criteria	Number Randomized, Analyzed Attrition	Intervention
Little 2008	England 64 centers General practice	Age 18-65 years, with LBP ≥3 months, score ≥4 on Roland disability scale, and current pain for ≥3 weeks Excluded: serious spinal disease, current nerve root pain, previous spinal surgery, inability to walk 100 m	579 randomized 463 completed 20% attrition	A. Exercise + 24 lessons in Alexander technique (n=71) B. Exercise + 6 lessons in Alexander technique (n=71) C. Exercise + massage (n=72) D. Exercise (n=72) E. 24 lessons in Alexander technique (n=73) F. 6 lessons in Alexander technique (n=73) G. Massage (n=75) H. Usual care (n=72)

Appendix E20. Data Abstraction of Randomized Controlled Trials of Exercise

Author, Year	Study Participants	Duration of Pain (acute, subacute, chronic)	Outcome Measures	Duration of Followup
Little 2008	Alexander technique control vs. massage vs. 6 lessons vs. 24 lessons vs. exercise control vs. exercise Mean age: 46 vs. 46 vs. 45 vs. 45 vs. 45 vs. 46 years Female sex: 73% vs. 78% vs. 63% vs. 64% vs. 68% vs. 71% Race: NR Median number of days in pain in previous 4 weeks: 24.5 vs. 28 vs. 28 vs. 28 vs. 28 vs. 28	Chronic; >3 months, average 243 ± 131 days of pain in past 12 months	RMQ, self-reported number of days of pain in previous 4 weeks, SF-36, Von Korff, Deyo, other belief scales	52 weeks

Appendix E20. Data Abstraction of Randomized Controlled Trials of Exercise

Author, Year	Results	Adverse Events Including Withdrawals	Funding Source	Quality Rating	Comments
Little 2008	A vs. B vs. C vs. D vs. E vs. F vs. G vs. H Roland disability score vs. usual care: -4.22 (p=0.002) vs. -2.98 (p=0.002) vs. -2.37 (p=0.015) vs. -1.65 vs. -4.14 (p<0.001) vs. -1.44 vs. -0.45 vs. 0 (ref) Number of days of pain in previous 4 months vs. usual care: -20 (p=0.001) vs. -13 (p=0.031) vs. -11 vs. -11 vs. -20 (p=0.001) vs. -13 (p=0.034) vs. -8 vs. 0 (ref) SF-36 PCS vs. usual care: 9.43 (p=0.015) vs. 8.53 (p=0.029) vs. 3.63 vs. -2.08 vs. 11.83 (p=0.002) vs. 2.04 vs. -1.45 vs. 0 (ref) SF-36 MCS vs. usual care: 4.99 vs. 0.64 vs. 2.73 vs. 0.72 vs. 3.74 vs. 4.10 vs. -2.11 vs. 0 (ref)	One patient reported that massage made their back pain worse	Medical Research Council	Fair	Deyo troublesomeness score, Von Korff score, back health transition, fear avoidance, and back health measures also reported, at one year and interim time points; although good quality, results are reported in a very confusing way; difficult to separate out exercise component

Appendix E20. Data Abstraction of Randomized Controlled Trials of Exercise

Author, Year	Country Number of Centers and Setting	Inclusion Criteria	Number Randomized, Analyzed Attrition	Intervention
Machado, 2010	Australia Multicenter (27) Primary care clinics	18 to 80 years old; present with a new episode of acute non-specific LBP; and be able and willing to visit one of the trial physical therapists for commencement of the McKenzie treatment program within 48 h of presentation to the physician. EXCLUSION nerve root compromise; 'red flags' for serious spinal pathology (for example, infection, fracture); spinal surgery in the past 6 months; pregnancy; severe cardiovascular or metabolic disease; or the inability to read and understand English.	Randomized, N = 148 Analyzed, N = 146 Attrition, 5.5% (8/146)	A: McKenzie method + first-line care (n = 73). Number of treatment sessions at discretion of the PT, with a max of 6 session over 3 weeks; encouraged to perform the prescribed exercises at home and to follow PT's postural advice at all times; some participants received lumbar support (93%, original McKenzie lumbar roll). B: First-line care only (n = 73). Consisted of advice to remain active and to avoid bed rest, reassurance of the favorable prognosis of acute LBP and instructions to take acetaminophen (paracetamol) on a time-contingent basis (NSAIDs not prescribed however those already on them were allow to remain on them); 3 weeks, return for followup as needed during that time

Appendix E20. Data Abstraction of Randomized Controlled Trials of Exercise

Author, Year	Study Participants	Duration of Pain (acute, subacute, chronic)	Outcome Measures	Duration of Followup
Machado, 2010	A vs B Mean age (years): 47.5 vs. 45.9 Female: 52% vs. 48% Race NR Pain etiology NR Referred pain to leg: 45% vs. 50% Previous LBP episode: 74% vs. 67% Baseline Pain (NRS): 6.6 ± 1.8 vs. 6.3 ± 1.9 Function (PSFS): 3.7 ± 1.6 vs. 3.4 ± 1.8 Disability (RMDQ): 13.7 ± 5.5 vs. 13.5 ± 5.3	Acute (defined as pain in the area between the 12th rib and buttock crease, w/w/o leg pain, of < 6 weeks duration, preceded by a period of at least 1 month without LBP in which the patient did not consult a health care practitioner). A vs. B < 2 weeks: 66% vs. 67% 2–6 weeks: 34% vs. 33%	Numeric Rating Scale (NRS), pain intensity on a scale of 0–10 (higher score = greater pain). Global perceived effect, scale of –5 (vastly worse) to 5 (completely recovered). Roland Morris Disability Questionnaire (RMDQ), disability on a scale of 0–24 (higher score = greater disability). Patient Specific Functional Scale (PSFS), function on a scale of 0 (unable to perform activity) to 10 (able to perform activity at pre-injury level). Persistent LBP at 3 months (yes/no), participants asked "During the past 3 months have you ever been completely free of low back pain? By this I mean no low back pain at all, and would this pain-free period have lasted for a whole month". Seeking of additional health-care	3 months

Appendix E20. Data Abstraction of Randomized Controlled Trials of Exercise

Author, Year	Results	Adverse Events Including Withdrawals	Funding Source	Quality Rating	Comments
Machado, 2010	A vs. B (treatment effects [95% CI] are model-based adjusted differences in outcomes between groups) Pain (NRS) **1 week: –0.4 (–0.8 to –0.1); p=0.02** (A, n = 70; B, n = 69) **3 weeks: –0.7 (–1.2 to –0.1); p=0.02** (A, n = 70; B, n = 68) **Mean pain over first 7 days: –0.3 (–0.5 to –0.0); p=0.02** (A, n = 70; B, n = 69) Function (PSFS) 1 week: 0.0 (–0.4 to 0.5); p=0.90 (A, n = 70; B, n = 68) 3 weeks: 0.0 (–0.7 to 0.8); p=0.90 (A, n = 70; B, n = 69) Disability (RMDQ) 1 week: –0.2 (–1.5 to 1.0); p=0.74 (A, n = 70; B, n = 68) 3 weeks: –0.3 (–2.3 to 1.6); p=0.74 (A, n = 70; B, n = 69) Global perceived effect 1 week: 0.5 (–0.0 to 1.1); p=0.07 (A, n = 70; B, n = 68) 3 weeks: 0.3 (–0.3 to 0.8); p=0.33 (A, n = 70; B, n = 69) Development of persistent LBP: 53% (37/70) vs. 47% (32/68); RR 1.1, 95% CI 0.8 to 1.6, p=0.49 Sought additional health care for LBP complaints: 7% (5/70) vs. 26% (18/68); RR 0.27, 95% CI 0.1 to 0.7, p=0.002	NR	research and development grant from the University of Sydney, Australia.		For all outcomes except pain, the additional effects of the McKenzie method were near zero at all time points and not statistically significant. Authors' conclusions: A treatment programme based on the McKenzie method does not produce appreciable improvements in pain, disability, function, global perceived effect or risk of developing persistent symptoms. Patients receiving only the recommended first-line care seek more additional health care than patients receiving the McKenzie method.

Appendix E20. Data Abstraction of Randomized Controlled Trials of Exercise

Author, Year	Country Number of Centers and Setting	Inclusion Criteria	Number Randomized, Analyzed Attrition	Intervention
Pengel, 2007	Australia, New Zealand Multicenter (7) PT clinics at University teach hospitals (6) and a primary care clinic (1)	18 to 80 years of age with nonspecific LBP lasting for at least 6 weeks but no longer than 12 weeks. EXCLUSION spinal surgery in the past 12 months, pregnancy, nerve root compromise, confirmed or suspected serious spinal abnormality (for example, infection, fracture, or the cauda equina syndrome), contraindications to exercise, and poor comprehension of the English language; participants who were receiving low back pain treatment other than spinal surgery were NOT excluded	Randomized, N = 260 Analyzed, N = 259 Attrition: 10.8% (28/259)	A: Exercise and advice (n = 63). B: Sham exercise and advice (n = 63). C: Exercise and sham advice (n = 65). D: Sham exercise and sham advice (n = 68). **Exercise**: Based on program described by Lindstrom and colleagues, to improve the abilities of participants to complete functional activities that they specified as being difficult to perform because of low back pain and includes: aerobic exercise (for example, a walking or cycling program), stretches, functional activities, activities to build speed, endurance, and coordination, and trunk- and limb-strengthening exercises. PTs used principles of cognitive-behavioral therapy and provided individualized home exercise programs; **Sham exercise:** Sham pulsed ultrasonography (5 minutes) and sham pulsed short-wave diathermy (20 minutes); **Advice:** Based on the program by Indahl and colleagues and aimed to encourage a graded return to normal activities. PTs explained the benign nature of LBP, addressed any unhelpful beliefs about back pain, and emphasized that being overly careful and avoiding light activity would delay recovery; **Sham advice:** Participants could talk about their LBP and any other problems, PT responded in a warm and empathic manner, displaying genuine interest, but did not give advice about the LBP. The 12 exercise or sham exercise sessions were delivered over 6 weeks: 3 sessions per week in weeks 1 and 2, 2 sessions per week in weeks 3 and 4, and 1 session per week in weeks 5 and 6. In weeks 1, 2, and 4, participants also received advice or sham advice.

Appendix E20. Data Abstraction of Randomized Controlled Trials of Exercise

Author, Year	Study Participants	Duration of Pain (acute, subacute, chronic)	Outcome Measures	Duration of Followup
Pengel, 2007	A vs. B vs. C vs. D Mean age (years): 50.1 vs. 51.2 vs. 48.0 vs. 50.0 Female: 46% vs. 44% vs. 46% vs. 54% Race NR Pain etiology NR Previous episodes of LBP: 71% vs. 69% vs. 60% vs. 65% Referred pain to legs: 29% vs. 38%, vs. 31% vs. 29% Baseline Pain (NRS): 5.4 ± 2.2 vs. 5.5 ± 2.1 vs. 5.4 ± 1.9 vs. 5.3 ± 1.7 Function (PSFS): 3.8 ± 1.9 vs. 3.8 ± 1.8 vs. 3.7 ± 2.0 vs. 4.0 ± 1.7 Disability (RMDQ): 9.1 ± 4.8 vs. 8.2 ± 4.4 vs. 8.3 ± 5.0 vs. 8.1 ± 5.6 Global perceived effect: –0.4 ± 2.3 vs. 0.2 ± 2.3 vs. –0.3 ± 2.6 vs. 0.5 ± 2.3 Depression (DASS): 7.3 ± 8.8 vs. 7.4 ± 7.7 vs. 7.1 ± 7.8 vs. 7.1 ± 7.6 Anxiety (DASS): 4.7 ± 6.7 vs. 5.2 ± 7.4) vs. 6.2 ± 7.6 vs. 5.4 ± 6.9 Stress (DASS): 10.1 ± 9.0 vs. 11.7 ± 8.7 vs. 12.6 ± 9.1 vs. 11.7 ± 10.0	Mixed acute/subacute A vs. B vs. C vs. D 6–8 weeks: 48% vs. 51% vs. 45% vs. 47 9–11 weeks: 34% vs. 41% vs. 38% vs. 37% 12 weeks: 18% vs. 8% vs. 17% vs. 16%	Numeric Rating Scale (NRS), pain intensity on a scale of 0–10 (higher score = greater pain). Patient Specific Functional Scale (PSFS), function on a scale of 0 (unable to perform activity) to 10 (able to perform activity at pre-injury level). Global perceived effect, scale of –5 (vastly worse) to 5 (completely recovered). Roland Morris Disability Questionnaire (RMDQ), disability on a scale of 0–24 (higher score = greater disability). Depression Anxiety Stress Scales (DASS-21), score range for each subscale, 0–42 (higher score = higher depression, anxiety, stress)	12 months

Appendix E20. Data Abstraction of Randomized Controlled Trials of Exercise

Author, Year	Results	Adverse Events Including Withdrawals	Funding Source	Quality Rating	Comments
Pengel, 2007	Adjusted multivariable mixed model, relative change (95% CI) Exercise vs. No Exercise Pain (NRS) **6 weeks: –0.8 (–1.3 to –0.3), p=0.004** 3 months: –0.5 (–1.1 to 0.1), p=0.092 12 months: –0.5 (–1.1 to 0.2), p=0.138 Function (PSFS) 6 weeks: 0.4 (–0.2 to 1.0), p=0.174 3 months: 0.5 (0.0 to 1.1), p=0.063 12 months: 0.5 (–0.1 to 1.0), p=0.094 Disability (RMDQ): 6 weeks: –0.8 (–1.8 to 0.3), p=0.141 3 months: –0.1 (–1.2 to 1.1), p=0.901 12 months: –0.3 (–1.6 to 0.9), p=0.597 Global perceived effect **6 weeks: 0.5 (0.1 to 1.0), p=0.017** **3 months: 0.5 (0.1 to 1.0), p=0.030** 12 months: 0.4 (–0.1 to 1.0), p=0.134 Depression (DASS) 6 weeks: –0.7 (–2.5 to 1.2), p=0.47 3 months: –0.3 (–2.1 to 1.6), p=0.78 12 months: –0.6 (–2.6 to 1.3), p=0.51	Mild adverse events (muscle soreness, increased pain, tiredness, nausea, weight gain, itchy scalp, and numbness in the legs): 8.1% (21/259) A vs. B vs. C vs. D 15.9% (10/63) vs. 4.8% (3/63) vs. 9.2% (6/65) vs. 2.9% (2/68) EPC calculated RR any exercise (groups A and C) vs. any sham ex or advice (Groups b and D) RR 3.3 (95% CI 1.2 to 8.7) p = 0.0105	National Health and Medical Research Council of Australia and the Australasian Low Back Pain Trial Committee. The funding sources had no role in study design; collection, analysis, or interpretation of the data; or writing of the report.		adjustment for the following baseline variables: currently taking pain medication, currently smoking, currently exercising, low back pain treatment in previous 6 weeks, and previous surgery for low back pain.

Appendix E20. Data Abstraction of Randomized Controlled Trials of Exercise

Author, Year	Country Number of Centers and Setting	**Inclusion Criteria**	Number Randomized, Analyzed Attrition	Intervention
Pengel, 2007 (cont.)				

Appendix E20. Data Abstraction of Randomized Controlled Trials of Exercise

Author, Year	Study Participants	Duration of Pain (acute, subacute, chronic)	**Outcome Measures**	Duration of Followup
Pengel, 2007 (cont.)				

Appendix E20. Data Abstraction of Randomized Controlled Trials of Exercise

Author, Year	Results	Adverse Events Including Withdrawals	Funding Source	Quality Rating	Comments
Pengel, 2007 (cont.)	Exercise + Advice vs. No Exercise or Advice Pain (NRS) **6 weeks: –1.5 (–2.2 to –0.7) ,p<0.001** **3 months: –1.1 (–2.0 to –0.3), p=0.009** 12 months: –0.8 (–1.7 to 0.1),p=0.069 Function (PSFS) **6 weeks: 1.1 (0.3 to 1.9), p=0.006** **3 months: 1.3 (0.6 to 2.1), p=0.001** **12 months: 1.1 (0.3 to 1.8), p=0.005** Disability (RMDQ): 6 weeks: –1.3 (–2.7 to 0.2), p=0.085 3 months: –1.0 (–2.6 to 0.6), p=0.20 12 months: –0.9 (–2.7 to 0.8), p=0.29 Global perceived effect **6 weeks: 1.3 (0.7 to 1.9), p<0.001** **3 months: 0.8 (0.2 to 1.5), p=0.017** 12 months: 0.8 (0.0 to 1.6), p=0.059 Depression (DASS) 6 weeks: 0.2 (–2.5 to 2.8), p=0.91 3 months: 0.2 (–2.4 to 2.7), p=0.91 12 months: –0.4 (–3.1 to 2.3), p=0.76				

Please see Appendix C. Included Studies for full study references.

Appendix E21. Data Abstraction of Systematic Reviews of Motor Control Exercise

Author, Year	Comparison	Data Sources	Number and Type of Studies	Interventions and Number of Patients	Methods for Rating Methodological Quality of Primary Studies
Bystrom 2013	1) MCE vs general exercise; 2) MCE vs minimal intervention (none, placebo or advice/ education); 3) MCE vs multimodal physical therapy; 4) MCE as part of multimodal intervention vs other components of that intervention	October 2012: PubMed, EMBASE, PEDro, and CINAHL databases; English only	16 RCTs (1 with 2 arms) (n = 1933) 80% with CBLP; included studies of subacute if duration >6 months; (?they define sub acute as 4-12 weeks) short (6 weeks–4 months), intermediate (4–8 months) and long term (8-15 months) followup	1) A: MCE versus B: general exercise (n = 741; 7 trials [1 with 2 arms]) 2) A: MCE versus C: minimal intervention (n = 541; 3 trials) 3) A: MCE versus D: multimodal PT (n = 499; 4 trials) 4) A: MCE as part of multimodal intervention versus E: other components of that intervention (n = 152; 2 trials)	10-point PEDro scale

Appendix E21. Data Abstraction of Systematic Reviews of Motor Control Exercise

Author, Year	Methods for Synthesizing Results of Primary Studies	Results	Adverse Events	Quality
Bystrom 2013	Random effects model (RevMan5) when data displayed statistical heterogeneity, fixed effects model (RevMan5) for homogenous data; heterogeneity assessed using I^2 statistic	A vs B Pain, weighted mean difference (95% CI) Short-term (6 trials [1 with 2 arms], n = 529): **−7.80 (−10.95 to −4.65)** Intermediate (3 trials, n = 523): **−6.06 (−10.94 to −1.18)** Long-term (4 trials [1 with 2 arms], n = 632): −3.10 (−7.03 to 0.83) Disability, weighted mean difference (95% CI) Short-term (6 trials [1 with 2 arms], n = 529): **−4.65 (−6.20 to −3.11)** Intermediate (3 trials, n = 523): **−4.86 (−8.59 to −1.13)** Long-term (3 trials, n = 523): **−4.72 (−8.81 to −0.63)** A vs C Pain, weighted mean difference (95% CI) Short-term (2 trials, n = 500): **−12.48 (−19.04 to −5.93** Intermediate (2 trials, n = 500): **−10.18 (−16.64 to −3.72**) Long-term (2 trials, n = 500): **−13.32 (−19.75 to −6.90)** Disability, weighted mean difference (95% CI) Short-term (3 trials, n = 541): **−9.00 (−15.28 to −2.73)** Intermediate (2 trials, n = 500): **−5.62 (−10.46 to −0.77)** Long-term (2 trials, n = 500): **−6.64 (−11.72 to −1.57)** A vs D Pain, weighted mean difference (95% CI) Short-term: lack of data Intermediate (4 trials, n = 499): **−14.20 (−21.23 to −7.16)** Long-term: lack of data Disability, weighted mean difference (95% CI) Short-term: lack of data Intermediate (2 trials, n = 256): **−12.98 (−19.49 to −6.47)** Long-term: lack of data A vs E No pooled analysis, trials reported at different time points (Figure 5 individual study results)	NR	

Please see Appendix C. Included Studies for full study references.

Appendix E22. Data Abstraction of Randomized Controlled Trials of Motor Control Exercise

Author, Year	Country Number of Centers and Setting	Inclusion Criteria	Number Randomized, Analyzed Attrition	Intervention	Study Participants	Duration of Pain (acute, subacute, chronic)
Inani, 2013	India; single center; outpatient physiotherapy department	Age group 20–50 years, male or female, diagnosed as non-specific LBP	Randomized, N = 30 Analyzed, N = 30 Attrition: 0% (0/30)	A: MCE; phase 1, patient taught to cognitively perform skilled activation of deep muscle while relaxing superficial muscle; phase 2, improve precision of task including coordinating with breathing, progression to static function position, progression to light dynamic task; phase 3, coordinate the activity of deep and superficial muscles without the global muscle taking over using closed and open chain activities; phase 4 function re-education, subject specific; exercises included transversus abdominus and lumbar multifidus exercises, slow curl-ups, sit-ups, oblique plan/side bridge, and bird-dog exercises.(n = 15) B: Conventional exercise; stretching, isometric exercises of spine (hollowing in abdominals, isometric for back extensors), bridging exercises, graded active flexion and extension exercises of spine (n = 15) For both groups: 4 weeks regular continuous monitoring in OPD followed by successive follow up 3x/wk for remaining 2 months; ergonomic advice given	A vs B Mean age (years): 27.8 vs. 32.9 Female: 40.0% vs 26.7% Race: NR Baseline Pain intensity (VAS): 6.3 ± 1.8 vs 7.0 ± 1.6 Function/disability (modified ODI): 19.0 ± 6.4 vs. 21.4 ± 5.4 Disability (%): 38.0 ± 13.0% vs 42.9 ± 11.0%	NR/unclear

Appendix E22. Data Abstraction of Randomized Controlled Trials of Motor Control Exercise

Author, Year	Outcome Measures	Duration of Followup	Results	Adverse Events Including Withdrawals	Funding Source	Quality Rating	Comments
Inani, 2013	Visual Analog Scale (VAS, 10 cm), rates amount of pain on scale of 0–10. Modified Oswestry Low Back Pain Disability Index (mODI), assesses limitations of various activities of daily living	3 months	A vs. B (mean ± SD, t-test) VAS pain (0–10 cm): **1.4 ± 0.9 vs. 2.3 ± 1.1, t = 2.273, p=0.031** Modified ODI: **4.4 ± 2.3 vs. 8.0 ± 3.2, t = 3.443, p=0.002** Disability (%): **8.8 ± 4.7% vs 16.0 ± 6.5%, t = 3.443, p= 0.002**	NR	NR		Compared with conventional exercises, MCEs were found to be more effective ($p<0.05$) in reducing pain and improving functional status by decreasing disability

Appendix E22. Data Abstraction of Randomized Controlled Trials of Motor Control Exercise

Author, Year	Country Number of Centers and Setting	Inclusion Criteria	Number Randomized, Analyzed Attrition	Intervention	Study Participants	Duration of Pain (acute, subacute, chronic)
Macedo, 2012	Australia, multicenter, primary care settings	chronic nonspecific LBP (3 months' duration) w/w/o leg pain; currently seeking care for LBP; 18-80 years of age; English speaker; patient suitable for active exercises; expected to continue residing in the Sydney or Brisbane region for the study duration; score of moderate or greater on question 7 or 8 of the SF-36. EXCLUDE: known or suspected serious pathology such as nerve root compromise (at least 2 of the following signs: weakness, reflex changes, or sensation loss, associated with the same spinal nerve); previous spinal surgery or scheduled for surgery during trial period; comorbid health conditions that would prevent active participation in exercise programs.	Randomized: N = 172 Analyzed: 2 months, n = 158; 6 and 12 months, n = 155 Attrition: 9.9% (17/172)	A: MCE; stage 1 = retraining program to improve activity of muscles assessed to have poor control and reduce activity of any muscle identified to be overactive; taught how to contract trunk muscles in a specific manner and progress until able to maintain isolated contractions of the target muscles for 10 reps of 10 secs each while maintaining normal respiration (feedback available to enhance learning); additional exercises for breathing control, spinal posture, and lower limb and trunk movement were performed; stage 2 = progression toward more functional activities, first using static and then dynamic tasks; motor control exercise guided by pain, and exercises were mostly pain-free. (n = 86) B: Graded activity; increase activity tolerance by performing individualized and submaximal exercises (based on activities that each participant identified as problematic/could not perform due to pain), in addition to ignoring illness behaviors and reinforcing wellness behaviors; activities progressed in a time-contingent manner; patients received daily quotas and instructed to only perform the agreed amount. (n = 86) Both groups to receive 14 individually supervised sessions of approximately 1 hour (12 initial treatment sessions over an 8-week period [2x wk for first 4 wks then 1x/wk for next 4 wks] and 2 booster sessions at 4 and 10 months following randomization; advised to do home exercises (type, intensity, number at discretion of PT) for 30 mins/wk in first month and 1 hr/wk in second month.	A vs B Mean age (years): 48.7 vs. 49.6 Female: 66.3% vs 52.3% Race: NR Baseline Pain intensity (NRS): 6.1 vs. 6.1 Function (PSFS): 3.7 vs. 3.6 Disability (RMDQ-24): 11.4 vs. 11.2 Quality of Life (SF-36 PCS and MCS): 43.9 vs. 43.8 and 52.9 vs. 54.7 Global impression of change (GPE): –1.4 vs. –1.6	chronic/mixed subacute; mean LBP duration (mos) (A vs. B): 74.0 vs. 100.7

Appendix E22. Data Abstraction of Randomized Controlled Trials of Motor Control Exercise

Author, Year	Outcome Measures	Duration of Followup	Results	Adverse Events Including Withdrawals	Funding Source	Quality Rating	Comments
Macedo, 2012	Numeric rating scale (NRS); average pain intensity over the last week on a scale of 0–10. Patient-Specific Functional Scale (PSFS): function on a scale of 0–10. Global Perceived Effect Scale: global impression of change (–5 to 5) Roland-Morris Disability Questionnaire (RMDQ-24): disability (0–24) Short Form-36 (SF-36) physical component score (PCS; 0–100) and mental component score (MCS; 0–100): quality of life	12 months	A vs B (mean ± SD; adjusted treatment effect (95% CI)) Pain intensity (NRS) baseline: 6.1 ± 1.9 vs. 6.1 ± 2.1 (NS) 2 months: 4.1 ± 2.5 vs. 4.1 ± 2.5, 0.0 (–0.7 to 0.8), p=0.94 6 months: 4.1 ± 2.5 vs. 4.1 ± 2.7, 0.0 (–0.8 to 0.8), p=0.99 12 months: 3.7 ± 2.7 vs. 3.7 ± 2.6, 0.1 (–0.7 to 0.9), p=0.83 Function (PSFS) baseline: 3.7 ± 1.6 vs. 3.6 ± 1.6 (NS) 2 months: 5.9 ± 2.1 vs. 5.5 ± 2.4, 0.2 (–0.5 to 0.9), p=0.53 6 months: 5.7 ± 2.3 vs. 5.7 ± 2.4, –0.2 (–0.9 to 0.5), p=0.53 12 months: 5.9 ± 2.2 vs. 6.1 ± 2.3, –0.4 (–1.1 to 0.3), p=0.25 Disability (RMDQ-24) baseline: 11.4 ± 4.8 vs. 11.2 ± 5.3 (NS) 2 months: 7.5 ± 6.4 vs. 8.0 ± 6.5, –0.8 (–2.2 to 0.7), p=0.30 6 months: 8.0 ± 7.1 vs. 8.6 ± 6.8, –0.8 (–2.3 to 0.6), p=0.26 12 months: 7.4 ± 6.7 vs. 8.0 ± 6.9, –0.6 (–2.0 to 0.9), p=0.45 Quality of Life, SF-36 PCS baseline: 43.9 ± 10.8 vs. 43.8 ± 10.3 (NS) 2 months: 51.6 ± 12.0 vs. 51.6 ± 13.4, –0.2 (–13.7 to 3.2), p=0.89 6 months: 52.6 ± 13.0 vs. 51.2 ± 13.8, 1.1 (–2.4 to 4.6), p=0.54 12 months: 53.8 ± 12.7 vs. 53.3 ± 14.0, –0.3 (–3.8 to 3.3), p=0.88	A vs. B Mild adverse effects: 22.1% (19/86) vs. 19.8% (17/86), RR = 1.12 (95% CI, 0.62 to 2.00), including (not reported by A vs. B): temporary exacerbation of pain, n = 27; increased pain of preexisting musculoskeletal conditions, n = 7; development of shin splints, n = 1; hip bursitis, n = 1 Withdrawals (by 12 months): 8.1% (7/86) vs. 2.3% (2/86), RR = 3.50 (95% CI, 0.75 to 16.37) RRs calculated by EPC	Australia's National Health and Medical Research Council; the funding source had no role in the planning or conduct of the study.		MCE and graded activity have similar effects (no significant difference between groups for any outcome)

Appendix E22. Data Abstraction of Randomized Controlled Trials of Motor Control Exercise

Author, Year	Outcome Measures	Duration of Followup	Results	Adverse Events Including Withdrawals	Funding Source	Quality Rating	Comments
Macedo, 2012 (continued)			Quality of Life, SF-36 MCS baseline: 52.9 ± 10.5 vs. 54.7 ± 11.5 (NS) 2 months: 56.0 ± 10.9 vs. 55.8 ± 13.0, 2.3 (–0.7 to 5.3), p=0.14 6 months: 54.9 ± 10.4 vs. 56.9 ± 11.8, 0.1 (–3.0 to 3.1), p=0.97 12 months: 57.0 ± 10.1 vs. 58.2 ± 10.8, 0.8 (–2.3 to 3.9), p=0.62 Global impression of change (GPE) baseline: –1.4 ± 2.3 vs. –1.6 ± 2.6 (NS) 2 months: 2.0 ± 1.9 vs. 2.0 ± 1.9, –0.1 (–1.0 to 0.7), p=0.74 6 months: 1.6 ± 2.4 vs. 1.5 ± 2.5, 0.0 (–0.9 to 0.8), p=0.91 12 months: 1.8 ± 2.5 vs. 1.5 ± 2.5, 0.2 (–0.6 to 1.0), p=0.62				

Please see Appendix C. Included Studies for full study references.

Appendix E23. Data Abstraction of Systematic Reviews of Pilates

Author, Year	Comparison	Data Sources	Number and Type of Studies	Interventions and Number of Patients	Methods for Rating Methodological Quality of Primary Studies
Wells 2014	Pilates vs standard care and physical activity Pilates vs other	10 data bases; Cumulative Index to Nursing and AlliedHealth Literature; Cochrane Library; Medline;	14 RCTS; CLBP of > 3months duration; if studies included	A. Pilates (n = xx; 14 studies) B . standard care and physical activity (n =);vs massage (n =); vs. other exercise (n=)	Yes: Modified Guidelines for use of the McMasters Critical Appraisal Form for Quantitative Studies

Appendix E23. Data Abstraction of Systematic Reviews of Pilates

Author, Year	Methods for Synthesizing Results of Primary Studies	Results	Adverse Events	Quality
Wells 2014	qualitative synthesis due to heterogeneity;	A vs B Abstract outcomes in the following order (when reported): Pain Function Quality of life	A vs B	Moderate (provisional)

Please see Appendix C. Included Studies for full study references.

Appendix E24. Data Abstraction of Randomized Controlled Trials of Tai Chi

Author, Year	Country Number of Centers and Setting	Inclusion Criteria	Number Randomized, Analyzed Attrition	Intervention	Study Participants	Duration of Pain (acute, subacute, chronic)	Outcome Measures
Hall 2011	Australia Community setting	Age 18-70 years, with persistent nonspecific LBP and moderate pain or moderate activity limitation Excluded: known or suspected serious spinal pathology, scheduled for spinal surgery, or contraindicated for exercise	160 randomized 151 completed 5.6% attrition	A. Tai chi, 18 sessions over 10 weeks (n=80) B. Waitlist (n=80)	A vs. B Mean age: 43 vs. 44 years Female sex: 79% vs. 70% Race: NR Pain duration >3 months: 100% vs. 100%	Chronic (100% with pain > 3 months)	NRS (bothersomeness and pain), RMQ, PDI, QBPDS, PSFS, GPE
Weifen 2013	China Single center University medical center	Age 25-45 years, non-specific LBP with duration 1-5 years, mean VAS in previous week of 4, and not involved in physical therapy in previous 3 months	320 randomized Number completed NR Attrition NR	A. Tai chi chuan (n=141) B. Backward walking (n=47) C. Jogging (n=47) D. Swimming (n=38) E. No exercise (n=47)	A vs. B vs. C vs. D vs. E Mean age: 37.5 vs. 38.2 vs. 37.2 vs. 37.5 vs. 38.1 years Female sex: 39% vs. 45% vs. 40% vs. 45% vs. 40% Race: NR Mean VAS: 5.3 vs. 5.2 vs. 5.0 vs. 5.2 vs. 5.1 Mean duration of pain: 2.1 vs. 2.1 vs. 1.9 vs. 2.0 vs. 2.2 years	Chronic (mean duration 2.1 ± 0.8 years)	VAS

Appendix E24. Data Abstraction of Randomized Controlled Trials of Tai Chi

Author, Year	Duration of Followup	Results	Adverse Events Including Withdrawals	Funding Source	Quality Rating	Comments
Hall 2011	10 weeks	A vs. B Bothersomeness, NRS: 5.0-3.7 vs. 4.5-4.9; mean between-group difference 1.7 (95% CI 0.9 to 2.5) Pain, NRS: 4.4-3.4 vs. 4.4-4.7; mean between-group difference 1.3 (95% CI 0.7 to 1.9) PDI: 22.7-17.0 vs. 23.9-23.8; mean between-group difference 5.7 (95% CI 1.8 to 9.6) RMQ: 10.2-7.0 vs. 9.1-8.1; mean between-group difference 2.6 (95% CI 1.1 to 3.7) QBPDS: 29.2-22.0 vs. 30.2-29.6; mean between-group difference 6.6 (95% CI 2.4 to 10.7) PSFS: 3.5-4.7 vs. 4.0-4.1; mean between-group difference -1.0 (95% CI -1.7 to -0.4) GPE: 0.4-1.6 vs. -0.1-0.4: mean between-group difference -0.8 (95% CI -1.5 to -0.0); p=0.05 <u>Proportion achieving ≥30% improvement</u> Bothersomeness, NRS: 50% vs. 17.5%; NNT 4 Pain, NRS: 46.3% vs. 15%; NNT 4 PDI, 45% vs. 17.5%; NNT 4 RMQ: 50% vs. 23.8%; NNT 4 QBPDS: 40% vs. 7.5%; NNT 4 PSFS: 43.8% vs. 16.3%; NNT 4	Three participants reported a small initial increase in back pain symptoms that were alleviated by the third or fourth week, participant reported an increase in upper back pain that was alleviated once they corrected upper extremity posture.	Arthritis Foundation of Australia, Arthritis Care of the UK	Fair	
Weifen 2013	26 weeks	A vs. B vs. C vs. D vs. E VAS, 3 months: 2.7 vs. 3.3 vs. 3.4 vs. 2.8 vs. 3.6; p<0.05 for A vs. all other groups except D VAS, 6 months: 2.3 vs. 2.9 vs. 3.1 vs. 2.4 vs. 3.2; p<0.05 for A vs. all other groups except D	No adverse events were reported in any of the groups	NR	Poor	Poor reporting

Please see Appendix C. Included Studies for full study references.

Appendix E25. Trials of Yoga Included in the APS/ACP Review

Author, Year, Title	Purpose of Study	Study Design	Inclusion Criteria	Exclusion Criteria	Number of Treatment and Control Subjects (number approached, number eligible, number enrolled)
Galantino, 2004 The impact of modified Hatha yoga on chronic low back pain: a pilot study	To evaluate the efficacy of Iyengar yoga for chronic low back pain	RCT	30 to 65 years, low back pain for more than 6 months, had undergone more than 2 conservative medical interventions without relief	Previous yoga experience, current chronic systemic disease, change in pain medications in last 14 days or during the study	Number approached and eligible not reported 22 randomized (11 to yoga and 11 to control)
Sherman, 2005 Comparing yoga, exercise, and a self-care book for chronic low back pain	To evaluate the efficacy of yoga compared to conventional exercise therapy or a self-care book in patients with chronic low back pain	RCT	Patients 20 to 64 years old who had visited a primary care provider for back pain 3 to 15 months before the study	Complicated low back pain, back pain potentially attributable to specific underlying diseases or conditions, currently receiving other back pain treatments or had participated in yoga or exercise training for back pain in the past year, possible disincentive to improve, unstable medical or severe psychiatric conditions or dementia, contraindications to participation	653 approached 111 eligible 101 randomized (36 yoga, 35 exercise, 30 self-care book)

Appendix E25. Trials of Yoga Included in the APS/ACP Review

Author, Year, Title	Subject Age, Gender, Diagnosis	Country and Setting	Sponsor	Measures
Galantino, 2004 The impact of modified Hatha yoga on chronic low back pain: a pilot study	Age, gender, race: Not reported Duration of pain not reported Baseline Oswestry Disability Index score: 25 vs. 37	US Single center	Not stated	Oswestry Disability Index Beck Depression Inventory Sit and Reach Test Functional Reach Test
Sherman, 2005 Comparing yoga, exercise, and a self-care book for chronic low back pain	Mean age: 44 vs. 42 vs. 45 Female gender: 69% vs. 63% vs. 67% nonwhite race: 6% vs. 0% vs. 3% Pain >1 year: 75% vs. 57% vs. 70% Mean symptom bothersomeness (11 point scale): 5.4 vs. 5.7 vs. 5.4	USA Multicenter Recruited from primary care	National Center for Complementary and Alternative Medicine and the National Institute for Arthritis and Musculoskeletal and Skin Diseases	Roland Disability Scale (24-point scale) "Bothersomeness" of back pain: 0 (not at all) to 10 (extremely bothersome) SF-36 Degree of restricted activity Medication use

Appendix E25. Trials of Yoga Included in the APS/ACP Review

Author, Year, Title	Type of Intervention	Results
Galantino, 2004 The impact of modified Hatha yoga on chronic low back pain: a pilot study	A: Iyengar yoga therapy (therapeutic variations of classic poses, using a wide range of postures and supportive props), 12 sessions over 6 weeks B: Usual activities	Yoga vs. usual activities Oswestry Disability Index (change from baseline): -3.83 vs. 2.18 Beck Depression Inventory (change from baseline): -0.27 vs. 1.81 Proportion with lower scores on Oswestry Disability Index after intervention: 46% vs. 40% Proportion with lower scores on Beck Depression Inventory after intervention: 54% vs. 20%
Sherman, 2005 Comparing yoga, exercise, and a self-care book for chronic low back pain	A: Yoga: viniyoga (therapeutically oriented style) designed for persons with back pain, 12 weekly 75 minute classes B: Exercise: therapeutic exercise program similar in length to yoga intervention with educational talk, feedback from previous week, aerobic and strengthening exercises, stretching, and deep breathing C: Self-care book: The Back Pain Help book	Yoga vs. exercise Roland disability score (mean difference): -1.8 (-3.5 to -0.1) at 12 weeks (p=0.034) and -1.5 (-3.2 to 0.2) at 26 weeks (p=0.092) Symptom bothersomeness score (mean difference): -0.6 (-1.6 to -0.4) at 6 weeks (p=0.22), -1.4 (-2.5 to -0.2) at 26 weeks (p=0.018) Yoga vs. self-care book Roland disability score (mean difference): -3.4 (-5.1 to -1.6) at 12 weeks (p=0.0002) and -3.6 (-5.4 to -1.8) at 26 weeks (p<0.001) Symptom bothersomeness score (mean difference): -1.6 (-2.6 to -0.5) at 6 weeks (p=0.0025) and --2.2 (-3.2 to -1.2) at 26 weeks (p<0.001) Yoga vs. exercise vs. self-care Visits to health care providers for low back pain: 4/34 (12%) vs. 6/32 (19%) vs. 9/29 (31%)at 26 weeks (NS) Medication use at week 26: 21% vs. 50% vs. 59% (p<0.05 for A vs. B or C) SF-36: No differences

Appendix E25. Trials of Yoga Included in the APS/ACP Review

Author, Year, Title	Duration of Followup	Loss to Followup	Compliance to Treatment	Adverse Events and Withdrawals Due To Adverse Events	Quality Rating	Comments
Galantino, 2004 The impact of modified Hatha yoga on chronic low back pain: a pilot study	6 weeks	6/22 (all in control group)	Not assessed	Not assessed		
Sherman, 2005 Comparing yoga, exercise, and a self-care book for chronic low back pain	26 weeks	6/101 at 26 weeks	Median classes attended 9 for yoga and 8 for exercise, more than 75% of participants reported practicing >3 days a week	No serious adverse events 1 yoga participant discontinued because of migraines, 1 exercise participant strained back and saw chiropractor		

Appendix E25. Trials of Yoga Included in the APS/ACP Review

Author, Year, Title	Purpose of Study	Study Design	Inclusion Criteria	Exclusion Criteria	Number of Treatment and Control Subjects (number approached, number eligible, number enrolled)
Williams, 2005 Effect of Iyengar yoga therapy for chronic low back pain	To evaluate the efficacy of Iyengar yoga for chronic low back pain	RCT	nonspecific LBP for > 3 months, >18 years old, English-speaking, ambulatory	Nerve root compression, disc prolapse, spinal stenosis, tumor spinal infection, ankylosing spondylitis, spondylosis, spondylolisthesis, kyphosis or structural scoliosis, widespread neurological disorder, presentation as pre-surgical candidate, involved in litigation or compensation, cardiopulmonary co morbidity, pregnancy, BMI >35, major depression or substance abuse, practitioner of yoga	210 approached 70 eligible 60 randomized (30 to yoga and 30 to exercise education)

Appendix E25. Trials of Yoga Included in the APS/ACP Review

Author, Year, Title	Subject Age, Gender, Diagnosis	Country and Setting	Sponsor	Measures
Williams, 2005 Effect of Iyengar yoga therapy for chronic low back pain	Mean age: 49 vs. 48 years Female gender: 65 vs. 71% nonwhite race: 10% vs. 8% Duration of LBP: 11.3 vs. 11.0 years Baseline pain (VAS): 2.3 vs. 3.2	USA Single center Yoga center	West Virginia University	Functional disability: Pain Disability Index (7 to 70 scale) Short-form McGILL Pain Questionnaire VAS: 0 to 10 scale Present Pain Index: 0 (no pain) to 5 (excruciating pain) Fear of movement: Tampa Scale of Kinesiophobia four point scale (strongly disagree to strongly agree) Survey of Pain Attitudes:0 to 4 scale Coping Strategies Questionnaire-revised: 27 items, 0 to 6 scale Back Pain Self-efficacy Scale: 10 (low certainty) to 100 (totally certain) Pain medication usage

Appendix E25. Trials of Yoga Included in the APS/ACP Review

Author, Year, Title	Type of Intervention	Results
Williams, 2005 Effect of Iyengar yoga therapy for chronic low back pain	A: Iyengar yoga therapy (therapeutic variations of classic poses, using a wide range of postures and supportive props), 16 weekly 1.5 hour classes B: Exercise instruction from weekly newsletter	Yoga vs. exercise education Pain Disability Index, mean change at 7 months (7 to 70 scale): -8.5 vs. -10.4, p=0.009 Present Pain Index, mean change at 7 months (0 to 5 scale): -0.5 vs. -0.9, p=0.140 VAS, mean change at 7 months (0 to 10 scale): -1.2 vs. -1.6, p=0.398 Pain medication 'success' at 7 months: 15/16 (94%) vs. 10/19 (53%) Survey of pain attitudes, fear of movement, self-efficacy, coping strategies: No differences

Appendix E25. Trials of Yoga Included in the APS/ACP Review

Author, Year, Title	Duration of Followup	Loss to Followup	Compliance to Treatment	Adverse Events and Withdrawals Due To Adverse Events	Quality Rating	Comments
Williams, 2005 Effect of Iyengar yoga therapy for chronic low back pain	7 months	18/60 discontinued or lost to followup	Patients in yoga group practiced an average of 52.3 minutes per week	Not assessed		

Please see Appendix C. Included Studies for full study references.

Appendix E26. Data Abstraction of Systematic Reviews of Yoga

Author, Year	Comparison	Data Sources	Number and Type of Studies	Interventions and Number of Patients	Methods for Rating Methodological Quality of Primary Studies	Methods for Synthesizing Results of Primary Studies
Cramer 2013	Yoga vs usual care (2 RCTs) Yoga vs education (7 RCTs) Yoga vx exercise (3 studies);	January 2012: Medline, EMBASE, the Cochrane Library, PsycINFO, and CAMBASE; no language restrictions	10 RCTs in qualitative synthesis; Two citations with different outcomes from same trial, treated as single study8 included in quantitative synthesis; 9/10 studies included CLBP patients; 1 included acute, subacute or chronic;	A. Yoga B. Usual care C. Education D. Exercise TOTAL n for each intervention unclear across all studies; Total N for all studies = 1067	2009 Updated Method Guidelines for Systematic Reviews in the Cochrane Back Review Group	Random effects model (RevMan) - SMD (95% CI) for continuous outcomes (negative value favors Yoga) with use of Cohen categories for overall effect size; RR (95% CI) for dichotomous outcomes; Order of priority for analysis of overall effect - no treatment, usual care, education, exercise

Appendix E26. Data Abstraction of Systematic Reviews of Yoga

Author, Year	Results	Adverse Events	Quality
Cramer 2013	**A vs any control** SMD (95% CI); p-value test for effect Short term (measures closest to 12 weeks, overall): Pain (6 studies): SMD -0. 48 (95%CI -0.65 to -0.31); p<0.00001;I-sq 0% Back-specific disability (8 studies): SMD -0.59 (-0.87 to -0.30);p<0.0001; I-sq 59% HRQOL (4 studies): SMD 0.41 (-0.11 to 0.93) p=0.12; I-sq = 72% Global improvement (2 studies) RR 3.27 (95% CI 1.89 to 5.66); p<0.01; I-sq = 0% Long Term (measures closest to 12 months, overall): Pain (5 studies): SMD -0.33 (95%CI -0.59 to -0.07) p=0.01;I-sq = 48% Back-specific disability (5 studies): SMD -0.35 (-0.55 to -0.15); p=0.0007; I-sq = 20% HRQOL (2 studies): SMD 0.18 (-0.05 to 0.41);p=0.13; I-sq = 0% **By control group:** **A vs. B***:* Short term back-specific disability (2 studies, n=106): SMD -0.65 (-1.62 to 0.33);p=0.20; I-sq =62% **A vs C:** Short-term: Pain (5 studies): SMD -0.45 (-0.63 to -0.26); p<0.01; I-sq=0% Back-specific disability (5 studies): SMD 0.45 (-0.65 to -0.25); p<0.01; I-sq=8% HRQOL (3 studies): SMD 0.25 (0.02 to 0.47) p=0.03; I-Sq= 0% Long term: Pain (4 studies): SMD -0.28 (-0.58 to -0.02); p=0.07; I-sq=47% Back-specific disability (4 studies): SMD 0.39 (-0.66 to -0.11); p<0.01; I-sq=40% HRQOL (2 studies): SMD 0.18 (-0.05 to 0.41); p=0.13; I-sq=0% **A vs. D*:*** Short-term, back-specific disability (disability) SMD -0.59 (-1.87 to 0.67); p=0.36; I^2=95%	Safety: 3 studies, 10.5 % (26/248); No major adverse events (1 study) 13 "mild to moderate" adverse events, 1 herniated disc in Yoga (1 study) 11 adverse events (mainly pain), 1 serious adverse event in yoga (severe pain?) (1 study) drop out due to respiratory infection (n = 2 in 2 studies?-unclear)' Denominators not provided	Good

Please see Appendix C. Included Studies for full study references.

Appendix E27. Data Abstraction of Randomized Controlled Trials of Yoga

Author, Year	Country Number of Centers and Setting	Inclusion Criteria	Number Randomized, Analyzed Attrition	Intervention	Study Participants	Duration of Pain (acute, subacute, chronic)
Nambi 2014	1 center: C.U. Shah Physiotherapy College, Gujarat, India	>18 years old with nonspecific LPB for 3 months; EXCLUDED: LBP due to nerve root compressing, disc prolapse, spinal stenosis, tumor, spinal infection, ankylosing spondylosis, spondylolisthesis, kypohsis or structural scoliosis, widespread neurological disorder, pre-surgical candidates, involved in litigation or compensation, compromised cardiopulmonary system, pregnant, BMI ?35, major depression or substance abuse, Yoga practitioners	Randomized: 60 Analyzed:54 Attrition: 10% (6/60)	A: 1 hour Iyengar class/week + 30 minute home practice, 5 days/week for 4 weeks; with props; 29 poses introduced in stages simple to progressively more challenging; At end of 4 weeks, participants encouraged to continue Yoga at home (n=30) B: Following 5-10 minute warm up (stretching exercises for soft tissue flexibility and range of motion); Taught specific exercises for strengthening abdominal and back muscles (depending on clinical findings) 3 days/week with 5 repetitions in 3 sets with 30-s pause per set; repetitions gradually increased until reaching 15 for 4 weeks: instructed to refrain from other back exercises, strenuous activities outside of normal activities of daily living during study (n=30)	A vs. B Mean age: 44.26 vs. 43.66 Female: 63.34% vs. 43.34% Race: NR Baseline Pain intensity (10 cm VAS,0= no pain , 10 = worst possible): 6.7 vs 6.7 Physically unhealthy days (from CDC HRQOL-4): 18 vs. 17.8 Mentally unhealthy days (from CDC HRQOL-4):17.0 vs. 17.4 Activity limitation days (from CDC HRQOL- 4): 16.7 vs 17.1	Chronic (>3 months), mean duration; nonspecific

Appendix E27. Data Abstraction of Randomized Controlled Trials of Yoga

Author, Year	Outcome Measures	Duration of Followup	Results
Nambi 2014	Pain: VAS (0-10) low back pain intensity, Centers for Disease Control and Prevention's (CDC)Health related quality of life questionnaire (HRQOL-4)- 1st question on general health was dichotomized as fair/poor or good/very good/excellent; other 3 questions - mean physically unhealthy days; mean mentally unhealthy days, mean number days poor physical or mental health kept from usual activities; Dichotomized with respect frequency in previous 30 days (≥ 14 days being frequent <14 being infrequent)	6 months	A vs. B Pain intensity (10 cm VAS, mean): 4weeks 3.8 vs 5.3; 6 months 1.8 vs. 3.8, % improvement 72.81% vs. 42.5%, p=0.001; SMD* 4 weeks (-1.66, 95% CI -2.24 to -1.07); 6 months (-2.17, 95% CI -2.81 to -1.53) Physically unhealthy days (mean): 4 weeks 7.7 vs 12.0; 6 months 2.6 vs. 6.9, % improvement 85.61% vs. 61.0%, p=0.001; Mentally unhealthy days (mean): 4 weeks 8.4 vs. 10.5; 6 months 2.6 vs. 6.9, % improvement 87.53% vs 71.37%, p=0.001; Activity limitation days (mean): 4 weeks 7.5 vs. 12.0; 6 months 2.0 vs. 5.0, % improvement 87.83% vs 70.59%, p=0.001; *SMD calculated from means and SD based on sample before attrition

Appendix E27. Data Abstraction of Randomized Controlled Trials of Yoga

Author, Year	Adverse Events Including Withdrawals	Funding Source	Quality Rating
Nambi 2014	**Not evaluated or reported**	**none**	**Poor**

Appendix E27. Data Abstraction of Randomized Controlled Trials of Yoga

Author, Year	Country Number of Centers and Setting	Inclusion Criteria	Number Randomized, Analyzed Attrition	Intervention	Study Participants	Duration of Pain (acute, subacute, chronic)
Saper, 2013	Boston Medical Center and 5 affiliated federally qualified community health centers	18-64 years old, current non-specific LBP persisting ≥12 weeks with average intensity of ≥4 for previous week (0 = no pain, 10 worst possible pain); sufficient English fluency to understand class instructions and complete questionnaires; EXCLUDED- known specific back pain pathology (spinal stenosis, spondylolisthesis, ankylosing spondylitis, severe scoliosis, malignancy, fracture); sciatic pain ≥ low back pain, spine surgery in previous 3 years, severe or progressive neurological deficit, new back pain treatment started within previous month or anticipated during study; pregnancy, Yoga practice in previous 6 months, active or planned workers compensation, disability or personal injury claims; perceived religious conflict.	Randomized: 95 Analyzed: at 6 weeks - 88; at 12 weeks 91 Attrition: 4.2 % (4/95)	A: 75 minute Hatha Yoga class once per week + recommended 30 minute home practice (n=49) B: 75 minute Hatha Yoga class twice per week + recommended 30 minute home practice (n=46) 12 weeks	Mean age: 46.4 vs. 48.7 years Female: 71% vs. 80% Race: White: 10% vs. 26% Black: 67% vs. 41% Other: 22% vs. 33% Hispanic: 6% vs. 13% Baseline pain (mean, low back pain intensity, 11 point numeric scale) 7.1 vs. 6.7 Back-specific function: (mean Roland-Morris Disability Questionnaire (RMDQ)) 13.7 vs. 13.6 SF-26 Physical: 37.5 vs 37.4; Mental 44.8 vs.44.1	Chronic (nonspecific, ≥ months); reported duration varied from <1 year to ≥10 years; statistical difference between groups at baseline treated as confounder

Appendix E27. Data Abstraction of Randomized Controlled Trials of Yoga

Author, Year	Outcome Measures	Duration of Followup	Results
Saper, 2013	Pain: low back pain intensity, 11 point numeric scale Back Specific: modified RMDQ (0-23 scale, higher scores reflect poorer function); Treatment adherence: attending ≥75% of recommended classes SF-36 Physical and Mental Pain medication use in previous week (yes/no); Overall improvement: 7 point Likert scale 0=extremely worsened, 6=extremely improved; Patient satisfaction: 5-point Likert scale 1=very satisfied, 5=very dissatisfied; Adverse events	12 weeks	A vs. B Change from baseline, *between group* difference in means: Pain: 6 weeks, −0.3 (−1.1 to 0.6), p=0.49; 12 weeks, 0.3 (−0.2 to 0.8), p=0.62 RMDQ: 6 weeks −0.6 (−2.7 to 1.6), p-0.62; 12 weeks, −0.1 (−1.4 to 1.2), p= 0.83 Pain: proportion experiencing ≥30% improvement from baseline: 29% (23/47) vs. 59%(26/44), p=0.33, RR 0.83 (95% CI 0.57 to 1.12): proportion experiencing ≥50% improvement from baseline: 57% (27/47) vs. 66% (29/44), p=0.41, RR 1.14 (95% CI 0.64 to 2.02; RMDQ proportion experiencing ≥30% improvement from baseline: 57% (27/47) vs. 66%(29/44), p=0.41, RR 0.87 (95% CI 0.63 to 1.21): proportion experiencing ≥50% improvement from baseline: 47% (22/47) vs. 50% (22/44), p=0.76, RR 0.94 (95% CI 0.61 to 1.43) Change from baseline, between group difference in means SF-36 Physical: 6 weeks 1.6 (95% CI -1.6 to 4.9) p=0.33; 12 weeks 0.2 (-3.4 to 3.7) p =0.93; SF-36 Mental 6 weeks 2.2 (-1.9 to 6.3) p=0.29; 12 weeks 1.5 (-2.6 to 5.6) p=0.47 A vs. B Other outcomes: Overall improvement scores: Same for A and B (mean 4.5, median 5) Satisfaction scores: mean 1.3 vs. 1.5, median 1 for both Medication use: Use of any pain medication decrease at 6 weeks (27% vs. 35%) and remained similar at 12 weeks, but NS difference in use of any pain medication or specific analgesic categories. Per protocol analyses did not reveal any statistical differences between groups for any outcome; Dose-response: Substantial variability in data; authors report potential for a "modest" dose-response" relationship with decrease in relationship slope for change in pain at approximately 12 class and approximately 9 classes for RMDQ -figure provided, but not detailed data -Authors indicated the conclusions regarding the causality of the association are not possible. Adherence: Class attendance: 65% (32/47) vs. 44% (20/44), p=0.04; weekly amount of home practice 93 vs. 97 minutes; home practice for both groups a median of 4 days/week; Hours of class + home 37 vs. 29, p =0.037

Appendix E27. Data Abstraction of Randomized Controlled Trials of Yoga

Author, Year	Adverse Events Including Withdrawals	Funding Source	Quality Rating
Saper, 2013	A vs. B Total: 27% (13/49) vs. 37% (17/46), p= 0.47; mostly musculoskeletal with LBP exacerbation most common; Related to intervention (total events): Definitely 1. vs. 2 ; Possibly 12 vs. 15; Serious 0 vs. 1 (persistent symptoms of cervical radiculopathy possibly from hyperextension in setting of preexisting cervical disc disease; Detailed list (number) of adverse events: Back pain 5 vs.8 Neck pain 1 vs. 3 (includes the participant with radiculopathy) Sciatica 1 vs. 2 Headache 1 vs. 2 Dizziness 1 vs. 1 Knee pain 1 vs. 0 Ankle pain 0 vs. 1 Shoulder pain 1 vs. 0 Abdominal pain 1 vs. 0 Wheezing 1 vs. 0	NCCAM, NIH RO1 grant	Fair

Please see Appendix C. Included Studies for full study references.

Appendix E28. Data Abstraction of Systematic Reviews of Psychological Therapies

Author, Year	Comparison	Data Sources	Number and Type of Studies	Interventions and Number of Patients	Methods for Rating Methodological Quality of Primary Studies
Henschke (Cochrane) 2011	Behavioral vs. waiting list control	Cochrane Back Review Group Trials Register (2/2009); The Cochrane Library (2009, issue 2); MEDLINE (through 2/2009); EMBASE (1988 - 2/2009); PsycINFO (1974-2/2009) No language restrictions.	3 RCTs (n=74) RoB: 0 low, 3 high Follow-up: post-treatment only Diagnosis: Nonspecific chronic (12+ weeks) LBP (all) Age: 18-65	A. Respondent therapy (progressive relaxation) (n=39) B. Waiting list control (n=35)	Risk of bias (Cochrane Back Review Group)
Henschke (Cochrane) 2011	Behavioral vs. waiting list control	Cochrane Back Review Group Trials Register (2/2009); The Cochrane Library (2009, issue 2); MEDLINE (through 2/2009); EMBASE (1988 - 2/2009); PsycINFO (1974-2/2009) No language restrictions.	4 RCTs (n=108) RoB: 3 low, 1 high Follow-up: post-treatment only Diagnosis: Nonspecific chronic (12+ weeks) LBP (all) Age: 18-65	A. Respondent therapy (EMG biofeedback) (n=56) B. Waiting list control (n=52)	Risk of bias (Cochrane Back Review Group)
Henschke (Cochrane) 2011	Behavioral therapy vs. waiting list control	Cochrane Back Review Group Trials Register (2/2009); The Cochrane Library (2009, issue 2); MEDLINE (through 2/2009); EMBASE (1988 - 2/2009); PsycINFO (1974-2/2009) No language restrictions.	4 RCTs (n=243) RoB: 3 low, 1 high Follow-up: post-treatment only Diagnosis: Nonspecific chronic (12+ weeks) LBP (all) Age: 18-65	A. Operant therapy (n=142) B. Waiting list control (n=101)	Risk of bias (Cochrane Back Review Group)

Appendix E28. Data Abstraction of Systematic Reviews of Psychological Therapies

Author, Year	Methods for Synthesizing Results of Primary Studies	Results	Adverse Events
Henschke (Cochrane) 2011	meta-analysis Note. Negative mean difference (MD) or standardized MD (SMD) favors treatment A.	**Pain intensity (VAS, 0-100):** **Post-treatment MD: -19.77 (95% CI -34 to -5.20), p=0.0078 (3 studies, N=74) (SOE: low)** **Functional status (generic) (various scales):** **Post-treatment SMD: -0.88 (95% CI -1.36 to -0.39), p=0.00041 (3 studies, N=74) (SOE: low)** Depression (Beck Depression Inventory, 0-63): Post-treatment MD: -6.80 (95% CI -20 to 6.12), p=0.30 (2 studies, N=58) (SOE: very low)	NR
Henschke (Cochrane) 2011	meta-analysis of 3 studies (not Bush) Note. Negative mean difference (MD) or standardized MD (SMD) favors treatment A.	**Pain intensity (various scales)** **Post-treatment SMD: -0.80 (95% CI -1.32 to -0.28) p=0.0025 (3 studies, N=64) (SOE: low)** Functional status (generic) (various scales): Post-treatment SMD: -0.17 (95% CI -1.56 to 1.22), p=0.81 (2 studies, N=44) (SOE: very low) Results for Bush study (not poolable): no differences between groups in pain or functional status.	NR
Henschke (Cochrane) 2011	meta-analysis of up to 3 studies (not Kole-Snijders 1996) Note. Negative mean difference (MD) or standardized MD (SMD) favors treatment A.	**Pain intensity (various scales):** **Post-treatment SMD: -0.43 (95% CI, -0.75 to -0.11) p=0.0091 (3 studies, N=153) (SOE: moderate)** Functional status (generic) (Sickness Impact Profile, 0-136): Post-treatment MD: -1.18 (95% CI -3.53, 1.18), p=0.33 (2 studies, N=87) (SOE: low) Depression (various scales: Post-treatment SMD: -0.11 (95% CI -0.67 to 0.44), p=0.69 (2 studies, N=103) (SOE: low)	NR

Appendix E28. Data Abstraction of Systematic Reviews of Psychological Therapies

Author, Year	Comparison	Data Sources	Number and Type of Studies	Interventions and Number of Patients	Methods for Rating Methodological Quality of Primary Studies
Henschke (Cochrane) 2011	Behavioral therapy vs. waiting list control	Cochrane Back Review Group Trials Register (2/2009); The Cochrane Library (2009, issue 2); MEDLINE (through 2/2009); EMBASE (1988 - 2/2009); PsycINFO (1974-2/2009) No language restrictions.	2 RCTs (n=68) RoB: 0 low, 2 high Follow-up: post-treatment only Diagnosis: Nonspecific chronic (12+ weeks) LBP (all) Age: 18-65	A. Cognitive therapy (n=29) B. Waiting list control (n=39)	Risk of bias (Cochrane Back Review Group)
Henschke (Cochrane) 2011	Behavioral therapy vs. waiting list control	Cochrane Back Review Group Trials Register (2/2009); The Cochrane Library (2009, issue 2); MEDLINE (through 2/2009); EMBASE (1988 - 2/2009); PsycINFO (1974-2/2009) No language restrictions.	5 RCTs (n=239) RoB: 3 low, 2 high Follow-up: post-treatment only Diagnosis: Nonspecific chronic (12+ weeks) LBP (all) Age: 18-65	A. Cognitive-behavioral therapy (n=129) B. Waiting list control (n=110)	Risk of bias (Cochrane Back Review Group)
Henschke (Cochrane) 2011	Behavioral therapy vs. behavioral therapy	Cochrane Back Review Group Trials Register (2/2009); The Cochrane Library (2009, issue 2); MEDLINE (through 2/2009); EMBASE (1988 - 2/2009); PsycINFO (1974-2/2009) No language restrictions.	1 RCT (n=24) RoB: 0 low, 1 high Follow-up: post-treatment, 3 months Diagnosis: Nonspecific chronic (12+ weeks) LBP (all) Age: 18-65	A. Respondent therapy (EMG biofeedback) (n=12) B. Respondent therapy (progressive relaxation) (n=12)	Risk of bias (Cochrane Back Review Group)

Appendix E28. Data Abstraction of Systematic Reviews of Psychological Therapies

Author, Year	Methods for Synthesizing Results of Primary Studies	Results	Adverse Events
Henschke (Cochrane) 2011	meta-analysis Note. Negative mean difference (MD) or standardized MD (SMD) favors treatment A.	Pain intensity (various scales): Post-treatment SMD: -0.27 (95% CI -0.75 to 0.22), p=0.29 (2 studies, N=68) (SOE: low) Functional status (generic) (various scales): Post-treatment SMD: -0.15 (95% CI -0.64 to 0.33), p=0.53 (2 studies, N=68) (SOE: low)	NR
Henschke (Cochrane) 2011	meta-analysis Note. Negative mean difference (MD) or standardized MD (SMD) favors treatment A.	**Pain intensity (various scales):** **Post-treatment SMD: -0.60 (95% CI -0.97 to -0.22), p=0.0017 (5 studies, N=239) (SOE: low)** Functional status (generic) (various scales): Post-treatment SMD:-0.37 (95% CI -0.87, 0.13), p=0.15 (4 studies, N=134) (SOE: low) Depression (Beck Depression Inventory, 0-63): Post-treatment MD: -1.92 (95% CI -6.16, 2.32), p=0.38 (4 studies, N=194) (SOE: very low)	NR
Henschke (Cochrane) 2011	No pooling (single study) Note. Negative difference favors treatment A	Pain intensity (McGill Pain Questionnaire): Post-treatment, difference between groups:-11.59, p>0.05; 3 months, difference between groups: -17.00, p>0.05 Pain intensity (0-10 VAS) Post-treatment, difference between groups:-0.64, p=N; 3 months, difference between groups: -1.06, p>0.05 SOE: NR	NR

Appendix E28. Data Abstraction of Systematic Reviews of Psychological Therapies

Author, Year	Comparison	Data Sources	Number and Type of Studies	Interventions and Number of Patients	Methods for Rating Methodological Quality of Primary Studies
Henschke (Cochrane) 2011	Behavioral therapy vs. behavioral therapy	Cochrane Back Review Group Trials Register (2/2009); The Cochrane Library (2009, issue 2); MEDLINE (through 2/2009); EMBASE (1988 - 2/2009); PsycINFO (1974-2/2009) No language restrictions.	2 RCTs (n=93) RoB: 1 low, 1 high Follow-up: post-treatment, 6 months Diagnosis: Nonspecific chronic (12+ weeks) LBP (all) Age: 18-65	A. Cognitive therapy (n=49) B. Operant therapy (n=44)	Risk of bias (Cochrane Back Review Group)
Henschke (Cochrane) 2011	Behavioral therapy vs. behavioral therapy	Cochrane Back Review Group Trials Register (2/2009); The Cochrane Library (2009, issue 2); MEDLINE (through 2/2009); EMBASE (1988 - 2/2009); PsycINFO (1974-2/2009) No language restrictions.	1 RCT (n=47) RoB: 0 low, 1 high Follow-up: post-treatment, 6 months, 12 months Diagnosis: Nonspecific chronic (12+ weeks) LBP (all) Age: 18-65	A. Cognitive therapy (n=49) B. Respondent therapy (progressive muscle relaxation) (n=44)	Risk of bias (Cochrane Back Review Group)

Appendix E28. Data Abstraction of Systematic Reviews of Psychological Therapies

Author, Year	Methods for Synthesizing Results of Primary Studies	Results	Adverse Events
Henschke (Cochrane) 2011	meta-analysis Note. Negative mean difference (MD) or standardized MD (SMD) favors treatment A.	Pain intensity: Post-treatment SMD: 0.41 (95% CI -0.63 to 1.45), p=0.44 (2 studies, N=93) (moderate SOE) 6 months SMD: 0.35 (95% CI -0.64 to 1.35), p=0.48 (2 studies, N=82) (moderate SOE)	NR
Henschke (Cochrane) 2011	No pooling (single study) Note. Negative difference favors treatment A	Pain intensity (VAS): Post-treatment difference between groups: 1.00, p>0.05; 6 months: data NR, p>0.05; 12 months: data NR, p>0.05 Functional status (generic) (Sickness Impact Profile): 6 months, data NR, p>0.05; 12 months, data NR, p>0.05 Global measure of improvement (measure NR): 6 months, data NR, p>0.05; 12 months, data NR, p>0.05 SOE: NR	NR

Appendix E28. Data Abstraction of Systematic Reviews of Psychological Therapies

Author, Year	Comparison	Data Sources	Number and Type of Studies	Interventions and Number of Patients	Methods for Rating Methodological Quality of Primary Studies
Henschke (Cochrane) 2011	Behavioral therapy vs. behavioral therapy	Cochrane Back Review Group Trials Register (2/2009); The Cochrane Library (2009, issue 2); MEDLINE (through 2/2009); EMBASE (1988 - 2/2009); PsycINFO (1974-2/2009) No language restrictions.	No studies	A. Operant therapy (n=0) B. Respondent therapy (n=0)	
Henschke (Cochrane) 2011	Behavioral therapy vs. behavioral therapy	Cochrane Back Review Group Trials Register (2/2009); The Cochrane Library (2009, issue 2); MEDLINE (through 2/2009); EMBASE (1988 - 2/2009); PsycINFO (1974-2/2009) No language restrictions.	2 RCTs (n=61) RoB: 0 low, 2 high Follow-up: post-treatment, 6 months, 12 months Diagnosis: Nonspecific chronic (12+ weeks) LBP (all) Age: 18-65	A. Combination of cognitive and behavioral therapies (n=37) B. Cognitive therapy (n=24)	Risk of bias (Cochrane Back Review Group)

Appendix E28. Data Abstraction of Systematic Reviews of Psychological Therapies

Author, Year	Methods for Synthesizing Results of Primary Studies	Results	Adverse Events
Henschke (Cochrane) 2011			
Henschke (Cochrane) 2011	meta-analysis Note. Negative mean difference (MD) or standardized MD (SMD) favors treatment A.	Pain intensity (various scales): Post-treatment SMD: -0.24 (95% CI -1.36 to 0.87), p=0.67 (2 studies, N=61) (SOE: very low) 6 months SMD: -0.30 (95% CI -2.59 to 1.98), p=0.79 (2 studies, N=44) (SOE: very low) 12 months SMD: -0.89 (95% CI -3.64 to 1.87), p=0.53 (2 studies, N=48) (SOE: very low) Functional status (generic) (Sickness Impact Profile, 0-136): Post-treatment MD: -2.01 (95% CI -10 to 5.99), p=0.62 (2 studies, N=61) (SOE: low) 6 month MD: -3.20 (95% CI -16 to 10), p=0.64 (2 studies, N=47) (SOE: very low) 12 month MD: -2.23 (-13 to 8.13), p=0.67 (2 studies, N=51) Depression (Beck Depression Inventory, 0-63): Post-treatment MD: -3.10 (95% CI -11 to 5.23), p=0.47 (2 studies, N=61) (SOE: very low) 6 month MD: -4.66 (95% CI -11 to 1.61), p=0.15 (2 studies, N=47) (SOE: low) 12 month MD: -0.64 (95% CI -4.61 to 3.32), p=0.75 (2 studies, N=51) (SOE: low)	NR

Appendix E28. Data Abstraction of Systematic Reviews of Psychological Therapies

Author, Year	Comparison	Data Sources	Number and Type of Studies	Interventions and Number of Patients	Methods for Rating Methodological Quality of Primary Studies
Henschke (Cochrane) 2011	Behavioral therapy vs. behavioral therapy	Cochrane Back Review Group Trials Register (2/2009); The Cochrane Library (2009, issue 2); MEDLINE (through 2/2009); EMBASE (1988 - 2/2009); PsycINFO (1974-2/2009) No language restrictions.	4 RCTs (n=278) RoB: 3 low, 1 high Follow-up: post-treatment, 6 months, 12 months Diagnosis: Nonspecific chronic (12+ weeks) LBP (all) Age: 18-65	A. Combination of cognitive and behavioral therapies (n=144) B. Operant therapy (n=134)	Risk of bias (Cochrane Back Review Group)

Appendix E28. Data Abstraction of Systematic Reviews of Psychological Therapies

Author, Year	Methods for Synthesizing Results of Primary Studies	Results	Adverse Events
Henschke (Cochrane) 2011	meta-analysis of 3 RCTs (except Kole-Snijders) Note. Negative mean difference (MD) or standardized MD (SMD) favors treatment A.	Pain intensity (various scales) Post-treatment SMD:-0.15 (95% CI -0.46 to 0.16), p=0.35 (3 studies, N=161) (SOE: moderate) 6 months SMD: -0.23 (95% CI -0.57 to 0.11), p=0.19 (3 studies, N=139) (SOE: moderate) 12 months SMD:-0.31 (95% CI -0.65 to 0.03), p=0.073 (3 studies, N=140) (SOE: moderate) Functional status (generic) (various scales): Post-treatment SMD: 0.21 (95% CI -0.24 to 0.67), p=0.36 (2 studies, N=77) (SOE: low) 6 month SMD: -0.23 (95% CI -1.01 to 0.55), p=0.57 (2 studies, N=61) (SOE: low) 12 month SMD: -0.50 (95% CI -1.56 to 0.56), p=0.36 (2 studies, N=66) (SOE: low) Kole-Snijders 1996: Pain coping, pain control: results favored A (p<0.05), data NR.	NR

Appendix E28. Data Abstraction of Systematic Reviews of Psychological Therapies

Author, Year	Comparison	Data Sources	Number and Type of Studies	Interventions and Number of Patients	Methods for Rating Methodological Quality of Primary Studies
Henschke (Cochrane) 2011	Behavioral therapy vs. behavioral therapy	Cochrane Back Review Group Trials Register (2/2009); The Cochrane Library (2009, issue 2); MEDLINE (through 2/2009); EMBASE (1988 - 2/2009); PsycINFO (1974-2/2009) No language restrictions.	4 RCTs (n=157) RoB: 1 low, 3 high Follow-up: post-treatment, 6 months Diagnosis: Nonspecific chronic (12+ weeks) LBP (all) Age: 18-65	A. Combination of cognitive and behavioral therapies (n=50) B. Respondent therapy (n=47)	Risk of bias (Cochrane Back Review Group)

Appendix E28. Data Abstraction of Systematic Reviews of Psychological Therapies

Author, Year	Methods for Synthesizing Results of Primary Studies	Results	Adverse Events
Henschke (Cochrane) 2011	meta-analysis of 3 studies (not Rose 1997) Note. Negative mean difference (MD) or standardized MD (SMD) favors treatment A.	Pain intensity (various scales): Post-treatment SMD: 0.09 (95% CI -0.31 to 0.50), p=0.64 (3 studies, N=97) (SOE: low) 6 months SMD: 0.47 (95% CI -0.42 to 1.35), p=0.30 (2 studies, N=62) (SOE: low) Functional status (generic) (various scales): Post-treatment SMD: 0.38 (95% CI -0.02 to 0.78), p=0.065 (3 studies, N=97) (SOE: low) 6 month SMD: 0.13 (95% CI -0.81 to 1.07), p=0.78 (2 studies, N=62) (SOE: low) **Depression (Beck Depression Inventory, 0-63):** **Post-treatment SMD: 2.89 (95% CI 0.55 to 5.24), p=0.016 (3 studies, N=97) (SOE: low)** 6 month SMD: 1.84 (95% CI -0.43 to 4.11), p=0.11 (2 studies, N=62) (SOE: low) Rose 1997 RCT not included in pooled analyses: Pain, post-treatment & 6 months: p>0.05 (NS, data NR) Functional status, post-treatment & 6 months: p>0.05 (NS, data NR) Psychological domain, post-treatment & 6 months: p>0.05 (NS, data NR)	NR

Appendix E28. Data Abstraction of Systematic Reviews of Psychological Therapies

Author, Year	Comparison	Data Sources	Number and Type of Studies	Interventions and Number of Patients	Methods for Rating Methodological Quality of Primary Studies
Henschke (Cochrane) 2011	Behavioral therapy vs. usual care	Cochrane Back Review Group Trials Register (2/2009); The Cochrane Library (2009, issue 2); MEDLINE (through 2/2009); EMBASE (1988 - 2/2009); PsycINFO (1974-2/2009) No language restrictions.	2 RCTs (N=330) RoB: 0 low, 2 high Follow-up: post-treatment, 6 months Diagnosis: Nonspecific chronic (12+ weeks) LBP (all) Age: 18-65	A. Behavioral therapy (n=167) B. Usual care (n=163)	Risk of bias (Cochrane Back Review Group)
Henschke (Cochrane) 2011	Behavioral therapy vs. group exercise	Cochrane Back Review Group Trials Register (2/2009); The Cochrane Library (2009, issue 2); MEDLINE (through 2/2009); EMBASE (1988 - 2/2009); PsycINFO (1974-2/2009) No language restrictions.	2 RCTs (N=146) RoB: 1 low, 1 high Follow-up: post-treatment, 6 months, 12 months Diagnosis: Nonspecific chronic (12+ weeks) LBP (all) Age: 18-65	A. Behavioral therapy (n=73) B. Group exercise (n=73)	Risk of bias (Cochrane Back Review Group)

Appendix E28. Data Abstraction of Systematic Reviews of Psychological Therapies

Author, Year	Methods for Synthesizing Results of Primary Studies	Results	Adverse Events
Henschke (Cochrane) 2011	meta-analysis Note. Negative mean difference (MD) or standardized MD (SMD) favors treatment A.	**Pain intensity (VAS, 0-100):** **Post-treatment MD: -5.18 (95% CI -9.79 to -0.57), p=0.028 (2 studies, N=330) (SOE: moderate)** 6 months MD:-4.29 (95% CI -9.28 to 0.69), p=0.091 (2 studies, N=319) (SOE: moderate) Functional status (back-specific) (various scales): Post-treatment SMD: -0.20 (95% CI -0.41 to 0.02), p=0.077 (2 studies, N=330) (SOE: moderate) 6 month SMD: -0.12 (95% CI -0.34 to 0.10), p=0.28 (2 studies, N=319) (SOE: moderate)	NR
Henschke (Cochrane) 2011	meta-analysis Note. Negative mean difference (MD) or standardized MD (SMD) favors treatment A.	Pain intensity (Pain Rating Index, 0-45) Post-treatment MD: -2.31 (95% CI -6.33 to 1.70), p=0.26 (2 studies, N=146) (SOE: low) 6 months MD: 1.18 (95% CI -3.16 to 5.53), p=0.59 (2 studies, N=137) (SOE: moderate) 12 months MD: 0.14 (95% CI -4.40 to 4.67), p=0.95 (2 studies, N=136) (SOE: moderate) Depression (various scales): Post-treatment SMD: 0.25 (95% CI -0.07 to 0.58), p=0.13 (2 studies, N=146) (SOE: low) 6 months SMD: 0.02 (95% CI -0.32 to 0.35), p=0.92 (2 studies, N=137) (SOE: moderate) 12 months SMD: 0.07 (95% CI -0.27 to 0.41), p=0.68 (2 studies, N=136) (SOE: moderate)	NR

Appendix E28. Data Abstraction of Systematic Reviews of Psychological Therapies

Author, Year	Comparison	Data Sources	Number and Type of Studies	Interventions and Number of Patients	Methods for Rating Methodological Quality of Primary Studies
Henschke (Cochrane) 2011	Behavioral therapy vs. guideline-based care	Cochrane Back Review Group Trials Register (2/2009); The Cochrane Library (2009, issue 2); MEDLINE (through 2/2009); EMBASE (1988 - 2/2009); PsycINFO (1974-2/2009) No language restrictions.	1 RCT (N=114) RoB: 0 low, 1 high Follow-up: 6 months, 12 months Diagnosis: Nonspecific chronic (12+ weeks) LBP (all) Age: 18-65	A. Behavioral therapy (n=60) B. Guideline-based care (n=54)	Risk of bias (Cochrane Back Review Group)
Henschke (Cochrane) 2011	Behavioral therapy vs. guideline-based care	Cochrane Back Review Group Trials Register (2/2009); The Cochrane Library (2009, issue 2); MEDLINE (through 2/2009); EMBASE (1988 - 2/2009); PsycINFO (1974-2/2009) No language restrictions.	1 RCT (N=36) RoB: 0 low, 1 high Follow-up: posttreatment, 3 months Diagnosis: Nonspecific chronic (12+ weeks) LBP (all) Age: 18-65	A. Behavioral therapy (n=24) (2 different types of behavioral therapy, results presented as 2 groups but were combined for this outcome) B. Education (n=12)	Risk of bias (Cochrane Back Review Group)

Appendix E28. Data Abstraction of Systematic Reviews of Psychological Therapies

Author, Year	Methods for Synthesizing Results of Primary Studies	Results	Adverse Events
Henschke (Cochrane) 2011	No analysis performed; data available in appendix only	**Pain intensity (measure NR)** **6 months: data NR, favors behavioral therapy, p<0.05 (NS);** 12 months: data NR, p>0.05 (NS) Functional status (measure NR): 6 months: data NR, p>0.05 (NS); 12 months: data NR, p>0.05 (NS) SOE: NR	NR
Henschke (Cochrane) 2011	No analysis performed; data available in appendix only Note. Negative difference favors treatment A.	Pain (McGill Pain Questionnaire): Post-treatment, difference between groups: -6.7, p=NR (not calculable) 3 months, difference between groups: 3.55 p=NR (not calculable) Pain intensity (0-10 VAS) Post-treatment, difference between groups:-1.11, p=NR (not calculable) 3 months, difference between groups: 0.38, p=NR (not calculable) SOE: NR	NR

Appendix E28. Data Abstraction of Systematic Reviews of Psychological Therapies

Author, Year	Comparison	Data Sources	Number and Type of Studies	Interventions and Number of Patients	Methods for Rating Methodological Quality of Primary Studies
Henschke (Cochrane) 2011	Behavioral therapy vs. hypnosis	Cochrane Back Review Group Trials Register (2/2009); The Cochrane Library (2009, issue 2); MEDLINE (through 2/2009); EMBASE (1988 - 2/2009); PsycINFO (1974-2/2009) No language restrictions.	1 RCT (N=17) RoB: 0 low, 1 high Follow-up: posttreatment, 3 months Diagnosis: Nonspecific chronic (12+ weeks) LBP (all) Age: 18-65	A. Behavioral therapy (n=8) B. Hypnosis (n=7)	Risk of bias (Cochrane Back Review Group)
Henschke (Cochrane) 2011	Behavioral therapy plus physiotherapy vs. physiotherapy	Cochrane Back Review Group Trials Register (2/2009); The Cochrane Library (2009, issue 2); MEDLINE (through 2/2009); EMBASE (1988 - 2/2009); PsycINFO (1974-2/2009) No language restrictions.	2 RCTs (N=47) RoB: 0 low, 2 high Follow-up: post-treatment, 6 months Diagnosis: Nonspecific chronic (12+ weeks) LBP (all) Age: 18-65	A. Behavioral therapy plus physiotherapy (n=41) B. Physiotherapy (n=18)	Risk of bias (Cochrane Back Review Group)

Appendix E28. Data Abstraction of Systematic Reviews of Psychological Therapies

Author, Year	Methods for Synthesizing Results of Primary Studies	Results	Adverse Events
Henschke (Cochrane) 2011	No analysis performed; data available in appendix only Note. Negative difference favors treatment A.	Pain (VAS, 0-100): Post-treatment, difference between groups: -4.5, p>0.05 (NS) (not calculable) 3 months, difference between groups: -6.3p>0.05 (NS) (not calculable) Depression (measure NR): Post-treatment: data NR, p>0.05 (NS); 3 months: data NR, p>0.05 (NS) SOE: NR	NR
Henschke (Cochrane) 2011		Pain intensity (5-point scale) Post-treatment MD: -0.13 (95% CI -1.01 to 0.75), p=0.77 (2 studies, N=59) (SOE: low) 6 months MD: -0.11 (-0.67 to 0.44), p=0.69 (2 studies, N=45) (SOE: low) Functional status (generic) (Sickness Impact Profile, 0-136): Post-treatment MD: -6.26 (95% CI -13 to 0.19), p=0.057 (2 studies, N=59) (SOE: low) 6 months MD:-0.93 (95% CI -6.71 to 4.84), p=0.75 (2 studies, N=51) (SOE: low) Depression (Beck Depression Inventory, 0-63): Post-treatment MD: 1.56 (95% CI -1.71 to 4.83), p=0.35 (2 studies, N=59) (SOE: low) 6 months MD: 0.17 (95% CI -6.85 to 7.19), p=0.96 (2 studies, N=50) (SOE: low)	NR

Appendix E28. Data Abstraction of Systematic Reviews of Psychological Therapies

Author, Year	Comparison	Data Sources	Number and Type of Studies	Interventions and Number of Patients	Methods for Rating Methodological Quality of Primary Studies
Henschke (Cochrane) 2011	Behavioral therapy plus inpatient rehabilitation vs. inpatient rehabilitation	Cochrane Back Review Group Trials Register (2/2009); The Cochrane Library (2009, issue 2); MEDLINE (through 2/2009); EMBASE (1988 - 2/2009); PsycINFO (1974-2/2009) No language restrictions.	3 RCTs (N=435) RoB: 1 low, 2 high Follow-up: post-treatment Diagnosis: Nonspecific chronic (12+ weeks) LBP (all) Age: 18-65	A. Behavioral therapy plus inpatient rehabilitation (n=206) B. Inpatient rehabilitation (n=229)	Risk of bias (Cochrane Back Review Group)
Henschke (Cochrane) 2011	Behavioral therapy plus educational booklet/audio cassette vs. educational booklet/audio cassette	Cochrane Back Review Group Trials Register (2/2009); The Cochrane Library (2009, issue 2); MEDLINE (through 2/2009); EMBASE (1988 - 2/2009); PsycINFO (1974-2/2009) No language restrictions.	1 RCT (N=234) RoB: 1 low, 0 high Follow-up: NR Diagnosis: Nonspecific chronic (12+ weeks) LBP (all) Age: 18-65	A. Behavioral therapy plus educational booklet/audio cassette (n=116) B. Educational booklet/audio cassette (n=118)	Risk of bias (Cochrane Back Review Group)

Appendix E28. Data Abstraction of Systematic Reviews of Psychological Therapies

Author, Year	Methods for Synthesizing Results of Primary Studies	Results	Adverse Events
Henschke (Cochrane) 2011	meta-analysis of 2 RCTs (not Strong 1998) Note. Negative mean difference (MD) or standardized MD (SMD) favors treatment A.	Pain intensity (various scales): Post-treatment SMD: -0.14 (95% CI -0.34 to 0.05), p=0.15 (2 studies, N=405) (SOE: moderate)	NR
Henschke (Cochrane) 2011	No analysis performed; data available in appendix only Note. Negative difference favors treatment A.	Note. Length of follow-up NR. Pain intensity (VAS scale NR) difference between groups: -3.6 (95% CI -8.5 to 1.2), p>0.05 (NS) Function (back-specific) (Roland-Morris Disability Questionnaire) difference between groups: -0.6 (95% CI -1.6 to 0.4), p>0.05 (NS)	NR

Appendix E28. Data Abstraction of Systematic Reviews of Psychological Therapies

Author, Year	Comparison	Data Sources	Number and Type of Studies	Interventions and Number of Patients	Methods for Rating Methodological Quality of Primary Studies
Henschke (Cochrane) 2011	Behavioral therapy plus exercise therapy vs. exercise therapy	Cochrane Back Review Group Trials Register (2/2009); The Cochrane Library (2009, issue 2); MEDLINE (through 2/2009); EMBASE (1988 - 2/2009); PsycINFO (1974-2/2009) No language restrictions.	3 RCTs (N=262) RoB: 1 low, 2 high Follow-up: posttreatment, 4 months, 6 months, 12 months Diagnosis: Nonspecific chronic (12+ weeks) LBP (all) Age: 18-65	A. Behavioral therapy plus exercise (n=135) B. Exercise (n=127)	Risk of bias (Cochrane Back Review Group)

Appendix E28. Data Abstraction of Systematic Reviews of Psychological Therapies

Author, Year	Methods for Synthesizing Results of Primary Studies	Results	Adverse Events
Henschke (Cochrane) 2011	No pooling performed (clinical heterogeneity across studies); data available in appendix only Note. Negative difference favors treatment A.	Friedrich 1998 (N=98) Pain intensity (VAS, 0-100), 4 month difference between groups: -7.1, p<0.05 (not calculable) Disability (low-back outcome score), 4 month difference between groups: -6.2, p<0.05 (not calculable) Modified Waddel Score, 4 months: data NR, p>0.05 (NS) Smeets 2006 (N=116): "No clinically relevant differences" for post-treatment outcomes: Roland-Morris Disability Questionnaire, functional limitations, pain intensity." (data NR) Turner 1990 (N=48) Pain (McGill Pain Questionnaire): Post-treatment, difference between groups: -5.11, p<0.05 (not calculable) 6 months: data NR, p>0.05 (NR) 12 months: data NR, p>0.05 (NR) Function (Sickness Impact Profile): Post-treatment, difference between groups: -0.90, p<0.05 (not calculable) 6 months: data NR, p>0.05 (NR) 12 months: data NR, p>0.05 (NR) Depression (measure, scale NR): Post-treatment, difference between groups: -0.07, p=NR (not calculable) 6 months: data NR, p>0.05 (NR) 12 months: data NR, p>0.05 (NR) SOE NR	NR

Please see Appendix C. Included Studies for full study references.

Appendix E29. Data Abstraction of Randomized Controlled Trials of Psychological Therapies

Author, Year	Country Number of Centers and Setting	Inclusion Criteria	Number Randomized, Analyzed Attrition	Intervention	Study Participants
Behavioral therapy versus waiting list control					
Morone 2008 Mindfulness meditation for the treatment of chronic low back pain in older adults: a randomized controlled pilot study	United States Single center Adult pain clinic	Age ≥ 65 years; low back pain (moderate pain occurring daily or almost daily for ≥3 months; intact cognition (Mini-Mental Status Exam score ≥23) Exclude: Previous participation in a mindfulness meditation program; had "red flags" of a serious underlying illness (malignancy, infection, unexplained fever, weight loss, recent trauma) causing the pain; does not speak English	Randomized: 37 Analyzed: 25 Attrition: 68% (25/37) at 12 weeks	A: Respondent treatment (n=19) (mindfulness meditation) (eight 90-minute group sessions, one per week, plus meditation homework; sessions led by experienced health professionals with meditation training; techniques used were nonjudgmental body scan, sitting practice with focus on breathing, slow walking meditation with focus on body sensation and/or breathing; general emphasis on patience, nonjudging, "beginner's mind", acceptance, letting go, nonstriving and trust) B: Wait list control (n=18) (no interventions; participants were offered meditation intervention at 8 weeks)	A vs. B Mean age: 74 vs. 76 years Female: 53% vs. 61% Caucasian: 89% vs. 89% Baseline pain (0-45 McGill Pain Questionnaire Short-form, pain intensity): 15.5 vs.15.2 (mean) Baseline function (0-24 RDQ): 11.5 vs. 11.8 (mean) Other characteristics: Osteoarthritis is the cause of pain: 89% vs. 89% Use of opioids: 21% vs. 17% Complementary and alternative medicine therapy used in last year: 42% vs. 56% Folstein Mini-Mental State Exam (mean): 29 vs. 29 p>0.05 between groups for all baseline characteristics

Appendix E29. Data Abstraction of Randomized Controlled Trials of Psychological Therapies

Author, Year	Duration of Pain (acute, subacute, chronic)	Outcome Measures	Duration of Followup	Results
Behavioral therapy versus waiting list control				
Morone 2008 Mindfulness meditation for the treatment of chronic low back pain in older adults: a randomized controlled pilot study	Eligibility: chronic: ≥ 3 months; Mean duration: not reported	**Pain:** 0-90 Short Form McGill Pain Questionnaire (lower scores indicate lower pain **Pain:** 0-100 SF-36 Pain Scale (lower scores indicate greater pain) **Function:** 0-24 Roland Morris Disability Questionnaire (higher scores indicate greater disability) **Function:** 0-100 SF-36 Physical Function Scale (lower scores indicate greater disability) **Pain acceptance:** Chronic Pain Acceptance Questionnaire (CPAQ) Total Score (0-120) (lower scores indicate less pain acceptance) **Pain acceptance:** Chronic Pain Acceptance Questionnaire (CPAQ) Activities Engagement Subscore (0-66) (lower scores indicate less pain acceptance) **Quality of life:** 0-100 SF-36 Physical Health, Mental Health, and Global Health Scales (lower scores indicate lower quality of life)	Post-treatment (1 month post-treatment for group A only)	A vs. B **Pain** (mean, 0-90 McGill):15.5 vs. 15.2 at baseline, 13.7 vs. 15.7 post-treatment (p=0.16), 16.5 vs. NR at 1 month **Pain** (mean, 0-100 SF-36 Pain Scale): 35.5 vs. 35.7 at baseline, 39.9 vs. 38.8 post-treatment (p=0.31), 39.9 vs. NR at 1 month **Function** (mean, 0-24 RDQ): 11.5 vs. 11.8 at baseline, 9.4 vs. 10.6 post-treatment (p=0.25), 8.9 vs. NR at 1 month **Function** (mean, 0-100 SF-36 Physical Function Scale): 42.0 vs. 45.1 at baseline, 45.7 vs. 44.5 post-treatment (p=0.03), 45.8 vs. NR at 1 month **Pain acceptance** (mean, 0-120 CPAQ Total Score): 72.2 vs. 68.1 at baseline, 75.5 vs. 64.8 post-treatment (p=0.008), 74.5 vs. NR at 1 month **Pain acceptance** (mean, 0-66 CPAQ Activities Engagement Subscore): 47.7 vs. 47.9 at baseline, 50.3 vs. 43.4 post-treatment (p=0.004), 48.1 vs. NR at 1 month **Quality of life** (mean, 0-100 SF-36 Physical Health): 41.4 vs. 41.2 at baseline, 43.9 vs. 42.9 post-treatment (p=0.36), 44.6 vs. NR at 1 month **Quality of life** (mean, 0-100 SF-36 Mental Health): 41.7 vs. 40.8 at baseline, 45.7 vs. 43.2 post-treatment (p=0.30), 45.1 vs. NR at 1 month **Quality of life** (mean, 0-100 SF-36 Global Health): 40.4 vs. 40.3 at baseline, 44.7 vs. 42.9 post-treatment (p=0.27), 43.9 vs NR at 1 month

Appendix E29. Data Abstraction of Randomized Controlled Trials of Psychological Therapies

Author, Year	Adverse Events Including Withdrawals	Funding Source	Quality Rating	Comments
Behavioral therapy versus waiting list control				
Morone 2008 Mindfulness meditation for the treatment of chronic low back pain in older adults: a randomized controlled pilot study	Not reported	National Institutes of Health (grant funding)	Fair	The study concluded that function as measured by the SF-36 physical function subscale was statistically better in group A vs. B but the result does not look different (45.6 vs. 44.5) nor was it statistically significant according to my calculation.

Appendix E29. Data Abstraction of Randomized Controlled Trials of Psychological Therapies

Author, Year	Country Number of Centers and Setting	Inclusion Criteria	Number Randomized, Analyzed Attrition	Intervention	Study Participants
Siemonsma, 2013 Cognitive treatment of illness perceptions in patients with chronic low back pain: a randomized controlled trial	Netherlands Single center Outpatient rehabilitation center	Age 18-70 years; nonspecific low back pain with or without radiation to legs ≥ 3 months; current episode of back pain < 5 years; limitations of activity (RMDA score > 3); no previous multidisciplinary treatment for chronic low back pain Exclude: involvement in litigation for pain; serious psychological or psychiatric problems; substance abuse interfering with treatment; pregnancy	Randomized: 156 Analyzed: 139 Attrition:89% (136/156) at 18 weeks	A: Cognitive treatment of illness perceptions (n=104): 10-14 one hour individual treatment sessions provided by physical or occupational therapist; treatment mapped existing illness perceptions, challenged maladaptive illness perceptions, formulated, tested, and strengthened alternative illness perceptions B: Waiting list control (no treatment, no co-interventions permitted) (n=52); note that patients expected to enter cognitive treatment therapy at end of 18 weeks	A vs. B Mean age: 45 vs. 47 years Female: 54% vs. 60% Race: Not reported Baseline pain (0-100 VAS): 56 vs. 56 (mean) Baseline function (0-24 RDQ): 12.2 vs. 12.7 (mean) Other characteristics: Anxiety (0-24 HADS): 5.5 vs. 5.0 (median) Depression (0-24 HADS): 5.0 vs. 4.0 Overall complaints (90-450 SCL-90): 132 vs. 126 (median) Fear of movement (17-68 TSK-R): 29.1 vs. 28.3 p>0.05 between groups for all baseline characteristics

Appendix E29. Data Abstraction of Randomized Controlled Trials of Psychological Therapies

Author, Year	Duration of Pain (acute, subacute, chronic)	Outcome Measures	Duration of Followup	Results
Siemonsma, 2013 Cognitive treatment of illness perceptions in patients with chronic low back pain: a randomized controlled trial	Eligibility: chronic: ≥ 3 months; Median duration (A vs. B): 60 vs. 72 months	**Activity-specific pain:** 0-100 PSC (Patient Specific Complaints, lower scores indicate better performance) (primary outcome measure) **Function:** 0-100 QBPDS (Quebec Back Pain Disability Scale, lower scores indicate better functioning) **Illness perception:** IPQ-R (Illness Perceptions Questionnaire-Revised; scales vary, not summed)	Post-treatment	A vs. B **Activity-specific pain (mean, 0 to 100 PSC):** ~76 vs. ~70 at baseline, ~44 vs. ~64 post-treatment (values estimated from graph) **Activity-specific pain (mean improvement from baseline, 0 to 100 PSC):** -19.1 (95% CI -24.3 to -13.9) vs. -5.2 (95% CI -14.7 to 4.2) (p=0.018) post-treatment (similar results for adjusted analysis) **Activity-specific pain (% of patients with clinically relevant change: decrease of 18 to 24 mm)**: 49% (46/93) vs. 26% (12/46) post-treatment (OR 2.77 (95% CI 1.28 to 6.01)) **Function (0-100 QBPDS):** 40.4 vs. 40.3 at baseline; 36.9 vs. 38.7 post-treatment (p=0.27) **Illness perception, time line/duration (0-30 IPQ):** 23.6 vs. 23.3 at baseline; 23.9 vs. 23.5 post-treatment (p=0.741) **Illness perception, time line cyclical nature (4-20 IPQ)**: 13.6 vs. 13.0 at baseline, 14.1 vs. 12.4 post-treatment (p=0.004) **Illness perception, consequences (6-30 IPQ):** 19.0 vs. 18.2 at baseline, 17.7 vs. 18.2 post-treatment (p=0.063) **Illness perception, personal control (6-30 IPQ)**: 19.1 vs. 19.2 at baseline, 21.1 vs. 18.9 post-treatment (p=0.001) **Illness perception, treatment control (5-25 IPQ):** 17.1 vs. 17.1 at baseline, 15.9 vs. 16.8 post-treatment (p=0.113) **Illness perception, coherence (5-25 IPQ):** 14.3 vs. 13.7 at baseline, 11.7 vs. 12.7 post-treatment (p=0.024) I**llness perception, emotional response (6-30 IPQ):** 16.9 vs. 17.5 at baseline, 15.5 vs. 16.4 post-treatment (p=0.425)

Appendix E29. Data Abstraction of Randomized Controlled Trials of Psychological Therapies

Author, Year	Adverse Events Including Withdrawals	Funding Source	Quality Rating	Comments
Siemonsma, 2013 Cognitive treatment of illness perceptions in patients with chronic low back pain: a randomized controlled trial	Not reported	The Netherlands Organization for Health Research and Development grant	Fair	

Appendix E29. Data Abstraction of Randomized Controlled Trials of Psychological Therapies

Author, Year	Country Number of Centers and Setting	Inclusion Criteria	Number Randomized, Analyzed Attrition	Intervention	Study Participants
Behavioral therapy versus other intervention					
Morone 2009 A mind-body program for older adults with chronic low back pain: results of a pilot study	United States Single center Adult pain clinic	Age ≥ 65 years; low back pain (moderate pain occurring daily or almost daily for ≥3 months; intact cognition (Mini-Mental Status Exam score ≥23) Exclude: Previous participation in a mindfulness meditation program; had "red flags" of a serious underlying illness (malignancy, infection, unexplained fever, weight loss, recent trauma) causing the pain; does not speak English; serious hearing or vision impairment that would preclude responding to questionnaires; multiple recent falls or inability to stand independently; pain caused by injury in the previous 3 months.	Randomized: 40 Analyzed: 35 Attrition: 88% (35/40) at 16 weeks	A: Respondent treatment (n=20) (mindfulness meditation) (eight 90-minute group sessions, one per week, plus meditation homework; sessions led by experienced health professionals with meditation training; techniques used were nonjudgmental body scan, sitting practice with focus on breathing, slow walking meditation with focus on body sensation and/or breathing; general emphasis on patience, nonjudging, "beginner's mind", acceptance, letting go, nonstriving and trust) B: Health education program (n=20) (8 week program, 90-minute sessions, consisted of: lectures, group discussion, homework based on topics discussed: general theme of brain health, pain medications, complementary treatments for back pain, types of back pain, role of physical therapist in treating back pain, eating and health, and Alzheimer's disease.	NOTE- Demographics reported for patients analyzed only A vs. B Mean age: 78 vs. 73 years (p=0.03) (NOTE- all subsequent analyses adjusted for age) Female: 69% vs. 58% Caucasian: 94% vs. 80% Baseline pain: (mean, 0-90 McGill Total Score): ~15.5 vs. ~16.0 Baseline function (0-24 RDQ): ~9.0 vs. ~11.5 Other characteristics: Osteoarthritis is the cause of pain: 63% vs. 47% Use of opioids: 19% vs. 26% Folstein Mini-Mental State Exam (mean): 29 vs. 29 Treatment expectations (0-6, lower scores indicate lower expectations of treatment success): 4.63 vs. 4.84 p>0.05 between groups for all baseline characteristics except age as reported

Appendix E29. Data Abstraction of Randomized Controlled Trials of Psychological Therapies

Author, Year	Duration of Pain (acute, subacute, chronic)	Outcome Measures	Duration of Followup	Results
Behavioral therapy versus other intervention				
Morone 2009 A mind-body program for older adults with chronic low back pain: results of a pilot study	Eligibility: chronic: ≥ 3 months; Mean duration: not reported	**Pain:** 0-90 Short Form McGill Pain Questionnaire Total Score (lower scores indicate lower pain) **Pain:** 0-45 Short Form McGill Pain Questionnaire Current Pain Score (lower scores indicate lower pain) **Pain:** 0-100 SF-36 Pain Scale (lower scores indicate greater pain) **Function:** 0-24 Roland Morris Disability Questionnaire (higher scores indicate greater disability) (primary outcome measure) **Function:** 0-100 SF-36 Physical Function Scale (lower scores indicate greater disability) **Quality of life:** 0-100 SF-36 Role Limitations Due to Emotional Problems (lower scores indicate lower quality of life) **Global impression of improvement:** (patient-reported as "much improved", "minimally improved", "no change", or "minimally worse" **Chronic Pain Self-efficacy:** 0-100 Chronic Pain Self Efficacy Scale (measures patients' perceived ability to cope with chronic pain) (higher scores indicate greater self efficacy)	Post-treatment and 2 months post-treatment	A vs. B (all data estimated from graphs) **Pain** (mean, 0-90 McGill Total Score): ~15.5 vs. ~16.0 at baseline, ~11.5 vs. ~11.5 post-treatment, ~12 vs. ~11.5 at 2 months (p>0.05 for all timepoints) **Pain** (mean, 0-45 McGill Current Pain Score): ~3.0 vs. ~4.5 at baseline, ~2.5 vs. ~4 post-treatment, ~2 vs. ~3.5 at 2 months (p>0.05 for all timepoints) **Pain** (mean, 0-100 SF-36 Pain Scale): ~39.5 vs. ~40 at baseline, ~42.5 vs. ~39.5 post-treatment, ~41.5 vs. ~40.5 at 2 months (p>0.05 for all timepoints) **Chronic Pain Self Efficacy** (0-100): ~63 vs. ~64 at baseline, ~71 vs. ~66 post-treatment, ~78 vs. ~70 at 2 months (p>0.05 for all timepoints) **Function** (mean, 0-24 RDQ): ~9.0 vs. ~11.5 at baseline, ~7.5 vs. ~9 post-treatment, ~7.5 vs. ~10 at 2 months (p>0.05 for all timepoints) **Quality of life** (mean, 0-100 SF-36 Role Limitation due to Emotional Problems): ~33 vs. ~30 at baseline (p>0.05), ~34 vs. ~26 post-treatment (p<0.05), ~34 vs. ~28 at 2 months (p>0.05) **Global improvement** (% of patients who consider themselves "much improved"): 31% (5/16) vs. 11% (2/18) (p=0.26) post-treatment

Appendix E29. Data Abstraction of Randomized Controlled Trials of Psychological Therapies

Author, Year	Adverse Events Including Withdrawals	Funding Source	Quality Rating	Comments
Behavioral therapy versus other intervention				
Morone 2009 A mind-body program for older adults with chronic low back pain: results of a pilot study	"There were no adverse events reported"	National Institutes of Health (grant funding)	Fair	

Appendix E29. Data Abstraction of Randomized Controlled Trials of Psychological Therapies

Author, Year	Country Number of Centers and Setting	Inclusion Criteria	Number Randomized, Analyzed Attrition	Intervention	Study Participants
Comparisons of different behavioral therapies					
(no trials)					

Appendix E29. Data Abstraction of Randomized Controlled Trials of Psychological Therapies

Author, Year	Duration of Pain (acute, subacute, chronic)	Outcome Measures	Duration of Followup	Results
Comparisons of different behavioral therapies				
(no trials)				

Appendix E29. Data Abstraction of Randomized Controlled Trials of Psychological Therapies

Author, Year	Adverse Events Including Withdrawals	Funding Source	Quality Rating	Comments
Comparisons of different behavioral therapies				
(no trials)				

Appendix E29. Data Abstraction of Randomized Controlled Trials of Psychological Therapies

Author, Year	Country Number of Centers and Setting	Inclusion Criteria	Number Randomized, Analyzed Attrition	Intervention	Study Participants
Behavioral therapy plus other intervention versus other intervention alone					
Lamb 2010 Group cognitive behavioral treatment for low-back pain in primary care: a randomized controlled trial and cost-effectiveness analysis Lamb 2012 Group cognitive behavioral interventions for low back pain in primary care: extended followup of the back skills training trial	England Multicenter General family practice	Age ≥18 years; low back pain of at least moderate intensity for ≥ 6 weeks Exclude: Physician's belief that the pain is caused by infection, fracture, malignancy or other potential serious cause; severe psychiatric or psychological disorder; previous participation n cognitive behavioral intervention for low back pain.	Randomized: 701 Analyzed: 598 at 12 months (end of original study period according to published protocol); 395 at extended followup (mean 34 (20-50) months) Attrition: 85.3% (598/701) at 12 months (end of original study period according to published protocol); 56.3% (395/701) at extended followup (mean 34 (20-50) months)	A: Group cognitive behavioral therapy plus active management advisory consult (n=468) (CBT: One individual assessment session (<90 minutes) plus six 90-minute group therapy sessions (duration of therapy not reported) that targeted behaviors and beliefs about physical activity and avoidance of activity; primary care physicians told to avoid referrals during intervention but otherwise no attempt was made to control consultations in the followup period) B: Active management advisory consult alone (n=233) (one 15 minute session of active management advice-info on remaining active, avoiding bed rest, use of pain medication, and symptom management- plus informational book) (patients free to seek further care on their own)	A vs. B Mean age: 53 vs. 54 years Female: 59% vs. 61% Caucasian: 88% vs. 88% Baseline pain (0-100% modified Van Korff pain): 59 vs. 59 (mean) Baseline function (0-24 RDQ): 9 vs. 9 (mean) Function (0-100% Von Korff disability): 49 vs. 46 Other characteristics: Severity of back pain "very or extremely troublesome": 54% vs. 56% Severity of back pain "moderately troublesome": 46% vs. 44% Unable to work because of back pain: 11% vs. 9% Back pain every day in last 6 weeks: 67% vs. 70% Stiff or restricted movement: 67% vs. 70% Quality of life (-0.50-1.0 EQ-5D): not reported Quality of life (0-100 SF-12 physical): 37 vs. 38 (mean) Quality of life (0-100 SF-12 mental): 45 vs. 46 (mean) Pain Self-efficacy (0-60 Pain Self Efficacy): 40 vs. 41 (mean) Fear avoidance beliefs (0-24 Fear avoidance beliefs questionnaire): 14 vs. 14 (mean) p>0.05 between groups for all baseline characteristics

Appendix E29. Data Abstraction of Randomized Controlled Trials of Psychological Therapies

Author, Year	Duration of Pain (acute, subacute, chronic)	Outcome Measures	Duration of Followup	Results
Behavioral therapy plus other intervention versus other intervention alone				
Lamb 2010 Group cognitive behavioral treatment for low-back pain in primary care: a randomized controlled trial and cost-effectiveness analysis Lamb 2012 Group cognitive behavioral interventions for low back pain in primary care: extended followup of the back skills training trial	Eligibility: subacute to chronic: ≥ 6 weeks; Mean duration (A vs. B): 13 vs. 13 years	**Pain:** 0-100% modified Von Korff pain scale (lower scores indicate lower pain) (primary outcome measure) **Function:** 0-24 Roland Morris Disability Questionnaire (higher scores indicate greater disability) (primary outcome measure) **Function:** 0-100% modified Von Korff disability scale (lower scores indicate less disability) (primary outcome measure) **Quality of life:** -0.59 to 1 EQ-5D (lower scores indicate worse health related quality of life) **Quality of life:** 0-100 SF-12 physical and mental quality of life (lower scores indicate lower quality of life) **Pain Self-efficacy:** 0-60 Pain Self Efficacy Scale (higher scores indicate greater self efficacy) **Fear avoidance beliefs**: 0-24 Fear Avoidance Beliefs Questionnaire lower scores indicate lower fear avoidance beliefs) **Treatment benefit** (% of patients) **Treatment satisfaction** (% of patients) **Self-rated benefit:** scale or measure not reported thus outcomes not included here.	12 months (protocol; Lamb 2010A) >12 month extended followup (mean 34 (20-50) months) (Lamb 2012)	**A vs. B** **Pain** (mean change from baseline, 0-100% Von Korff pain): 12.2 vs. 5.4 at 3 months (p<0.0001), 13.7 vs. 5.7 at 6 months (p<0.0001),13.4 vs. 6.4 at 12 months (p<0.0001), 17.4 vs. 12.8 at mean 34 (20-50) months (p=0.107) **Function** (mean change from baseline, 0-24 RDQ): 2.0 vs. 1.1 at 3 months (p=0.0021), 2.5 vs. 1.0 at 6 months (p=0.0002), 2.4 vs. 1.1 at 12 months (p=0.0008), 2.9 vs. 1.6 at mean 34 (20-50) months (p=0.013) **Function** (mean change from baseline, 0-100% Von Korff disability): 13.2 vs. 8.9 at 3 months (p=0.0316), 13.9 vs. 5.7 at 6 months (p<0.0001),13.8 vs. 5.4 at 12 months (p<0.0001), 16.7 vs. 11.2 at mean 34 (20-50) months (p=0.039) **Quality of life** (mean change from baseline, -0.59 to 1 EQ-5D): -0.06 vs. 0.01 at 3 months (p=0.007), -0.05 vs. -0.03 at 6 months (p=0.382), -0.06 vs. -0.0003 at 12 months (p=0.027), -0.07 vs. -0.04 at mean 34 (20-50) months (p=0.387) **Quality of life** (mean change from baseline, 0-100 SF-12 physical): -3.7 vs. -1.5 at 3 months (p=0.0031), -3.6 vs. -1.8 at 6 months (p=0.0144), -4.9 vs. -0.8 at 12 months (p<0.0001) **Quality of life** (mean change from baseline 0-100 SF-12 mental): -1.3 vs. 0 at 3 months (p=0.1276), -2.5 vs. 0.09 at 6 months (p=0.0035), -0.9 vs. -0.7 at 12 months (p=0.8323) **Pain self-efficacy** (mean change from baseline 0-60 Pain Self Efficacy): -2.4 vs. 0.9 at 3 months (p<0.0001), -2.6 vs. 1.5 at 6 months (p<0.0001), -3.0 vs. 0.8 at 12 months (p<0.0001) **Fear avoidance beliefs** (mean change from baseline 0-24 Fear Avoidance Beliefs Questionnaire): 3.4 vs. 0.7 at 3 months (p=0.0004), 3.0 vs. -0.1 at 6 months (p<0.0001), 3.4 vs. 0.5 at 12 months (p<0.0001) **Treatment benefit** (% of patients who considered themselves recovered)**:** 59% (235/395) vs. 31% (62/197) at 12 months (p<0.0001) **Treatment satisfaction** (% of patients satisfied with treatment): 65% (212/328) vs. 28% (43/151) at 12 months (p=0.463)

Appendix E29. Data Abstraction of Randomized Controlled Trials of Psychological Therapies

Author, Year	Adverse Events Including Withdrawals	Funding Source	Quality Rating	Comments
Behavioral therapy plus other intervention versus other intervention alone				
Lamb 2010 Group cognitive behavioral treatment for low-back pain in primary care: a randomized controlled trial and cost-effectiveness analysis Lamb 2012 Group cognitive behavioral interventions for low back pain in primary care: extended followup of the back skills training trial	"There were no serious events attributable to either treatment."	National Institute for Health Research Health Technology Assessment Program	Fair	

Appendix E29. Data Abstraction of Randomized Controlled Trials of Psychological Therapies

Author, Year	Country Number of Centers and Setting	Inclusion Criteria	Number Randomized, Analyzed Attrition	Intervention	Study Participants
Vong 2011 Motivational enhancement therapy in addition to physical therapy improves motivational factors and treatment outcomes in people with low back pain: a randomized controlled trial	China Single center Physical therapy outpatient department	Age 18-65 years; chronic low back pain of at least 3 months' duration. Exclusion: pregnancy; cardiac pacemaker; pain from neurologic disorders or rheumatologic disease; consistent symptoms of sciatica; spondylolisthesis more than 1 cm; received physical therapy for low back pain in the past 3 months; psychiatric problems; received compensation for work-related disabilities	Randomized: 88 Analyzed: 76 Attrition: 86% (76/88)	A: Motivational enhancement treatment plus physical therapy (n=45) (physical therapy: see group B for details) (motivational enhancement: motivational enhancement given during the physical therapy sessions to enhance motivation and make appropriate behavioral changes) B: Physical therapy (n=43) (ten 30-minute sessions over 8 weeks, including 15 minutes of interferential (electro physical) therapy and a tailor-made back exercise program; interferential therapy employed 4 interferential suction electrodes placed over the L2 to S1 paraspinal muscles on both sides of the back and a current of 80-100Hz was used; physical therapy began with thorough assessment followed by a prescription of a specific set of exercises to include stretching/strengthening exercises for trunk and lower limbs; patients also requested to exercise at home every day)	NOTE- Demographics reported for patients analyzed only A vs. B Mean age: 45 vs. 45 years Female: 58% vs. 68% Race: not reported Baseline pain (0-10 VAS) (mean): 5.3 vs. 5.3 Baseline function (0-24 RDQ) (mean): 10.0 vs. 10.0 Other characteristics: Previous physical therapy: 16% vs. 29% Recurrent low back pain: 21% vs. 34% Regular analgesia: 32% vs. 29% SF-36 (0-100) physical function: 67 vs. 63 SF-36 (0-100) role-physical: 22 vs. 30 SF-36 (0-100) bodily pain: 41 vs. 49 (p=0.047) SF-36 (0-100) general health: 41 vs. 49 p>0.05 between groups for all baseline characteristics unless noted

Appendix E29. Data Abstraction of Randomized Controlled Trials of Psychological Therapies

Author, Year	Duration of Pain (acute, subacute, chronic)	Outcome Measures	Duration of Followup	Results
Vong 2011 Motivational enhancement therapy in addition to physical therapy improves motivational factors and treatment outcomes in people with low back pain: a randomized controlled trial	Eligibility: 3+ months (chronic) Mean duration (A vs. B): 41.6 vs. 51.0 months	**Pain:** 0-10 VAS) (lower scores indicate lower pain) **Function:** 0-24 Roland Morris Disability Questionnaire (higher scores indicate greater disability) **Quality of life:** 0-100 SF-36 (lower scores indicate greater pain) **Pain Self-efficacy:** 0-60 Pain Self Efficacy Questionnaire (higher scores indicate greater self efficacy)	1 month post-treatment	A vs. B **Pain** (mean 0-10 VAS): 5.3 vs. 5.3 at baseline; 3.1 vs. 3.9 at 1 month (p>0.05) **Function** (mean 0-24 RDQ): 10.0 vs. 10.1 at baseline; 5.6 vs. 7.6 at 1 month (p>0.05) **Quality of life** (mean 0-100 SF-36): SF-36 (0-100) physical function: 67 vs. 63 (p>0.05) at baseline; p> 0.05 at 1 month (data not reported) SF-36 (0-100) role-physical: 22 vs. 30 (p>0.05) at baseline; p> 0.05 at 1 month (data not reported) SF-36 (0-100) bodily pain: 41 vs. 49 (p=0.047) at baseline; p> 0.05 at 1 month (data not reported) SF-36 (0-100) general health: 41 vs. 49 (p>0.05) at baseline; p> 0.05 at 1 month (data not reported) **Pain self-efficacy** (mean 0-60 PSEQ): 39.5 vs. 40.5 at baseline (p>0.05); 45.4 vs. 45.6 at 1 month (p>0.05)

Appendix E29. Data Abstraction of Randomized Controlled Trials of Psychological Therapies

Author, Year	Adverse Events Including Withdrawals	Funding Source	Quality Rating	Comments
Vong 2011 Motivational enhancement therapy in addition to physical therapy improves motivational factors and treatment outcomes in people with low back pain: a randomized controlled trial	Not reported	None stated (noted that there was no commercial party funding or conflict of interest)	Fair	

Please see Appendix C. Included Studies for full study references.

Appendix 30. Data Abstraction of Systematic Reviews of Multidisciplinary Rehabilitation

Author, Year	Comparison	Data Sources and Dates	Type of Studies (sample sizes), Duration of follow up,	Interventions and Number of Patients	Techniques Evaluated, Duration and Number of sessions
Kamper, 2014	Multidisciplinary biopsychosocial rehab (MBR) 1. MBR (A) vs usual care (B) 2. MBR vs physical treatment (C) 3. MBR vs surgery (D) 4. MBR vs wait list (E)	CENTRAL, MEDLINE, EMBASE, PsycINFO and CINAHL databases, hand searches of the reference lists of included and related studies, forward citation tracking of included studies and screening of studies excluded in the previous version of this review Dates: 1998 - January and March 2014, no language restriction	41 RCTs of adult chronic mechanical or non-specific low back pain (≥12 weeks of pain) Short term outcomes = up to 3 months Med Term outcomes = >3 mo to <12 mo Long Term outcomes = >12 or more	Total participants = 6858 A vs B (n = 16 trials) A vs C (n = 19 trials) A vs D (n = 2 trials) A vs E (n = 4 trials) See results section for number of trials and participants	Multidisciplinary biopsychosocial rehab (MBR) (defined as a physical treatment + at least one element from biopsychosocial model, delivered by different providers but in an integrated fashion involving communication among providers). Clinicians included physicians, psychologists, physiotherapists, social workers, occupational workers and exercise therapists) 15 studies = high intervention intensity (>100 hrs contact delivered on daily basis) 15 studies = low intervention intensity (<30 hrs on non-daily basis) 11 studies = neither high nor low intensity

Appendix 30. Data Abstraction of Systematic Reviews of Multidisciplinary Rehabilitation

Author, Year	Methods for Rating Methodological Quality of Primary Studies	Methods for Synthesizing Results of Primary Studies	Results	Adverse Events	Quality
Kamper, 2014	GRADE and Cochrane Back Review Group (2009)	Meta-analysis using random effects models	A vs B Pain Short Term Outcome (n = 9 studies; 879 pts): SMD -0.55 (95% CI -0.83 to -0.28) Medium Term Outcome (n = 6 studies; 740 pts): SMD -0.60 (95% CI -0.85 to -0.34) Long term outcome (n=7; 821 pts): SMD -0.21 (95% CI -0.37 to -0.04) Back specific disability Short Term Outcome (n = 9 studies, 939 pts) SMD -0.41 (95% CI -0.62 to -0.19) Medium Term Outcome (n=6 studies; 786 pts) SMD -0.43 (95% CI -0.66 to -0.19) Long Term Outcome (n= 6; 722 pts) SMD -0.23 (95% CI -0.40 to -0.06) Work status Short Term Outcome (n = 2; 373 pts) OR 1.07 (95% CI 0.60 to 1.90) Medium Term Outcome (n = 3; 457 pts) OR 1.60 (95% CI 0.52 to 4.91) Long Term Outcome (n = 7, 1360 pts) OR 1.04 (95% CI 0.73 to 1.47) A vs C Pain Short Term Outcome (n = 12 studies; 1661 pts): SMD -0.30 (95% CI -0.54 to -0.06) Medium Term Outcome (n = 9 studies, 531 pts) SMD -0.28 (95% CI -0.54 to -0.02) Long Term Outcome (n= 9 studies, 872 pts) SMD -0.51 (95% CI -1.04 to 0.01)	Only reported in one study with no adverse events, otherwise not reported	High

Please see Appendix C. Included Studies for full study references.

Appendix E31. Data Abstraction of Randomized Controlled Trials of Multidisciplinary Rehabilitation

Author, Year	Country Number of Centers and Setting	Inclusion Criteria	Number Randomized, Analyzed Attrition	Intervention	Study Participants	Duration of Pain (acute, subacute, chronic)	Outcome Measures
Eisenberg, 2012	Boston, USA	LBP 3-12 weeks 18-70 years old Excluded: LBP < 21 days or >84 days, pain <3, history of back surgery in last 3 years, history of vertebral fracture or dislocation, progressive or severe neurological symptoms, spondylolisthesis, scoliosis, ankylosing spondylitis, pacemaker or ICD, systemic or visceral disease cause back pain, osteoporosis, taking steroids, pregnancy, history of cancer within 5 yrs, unexplained fever or weight loss, bleeding disorder, disabling condition, transplant, immunosuppression, IVDU, non-English speaking	20 randomized A: 14 allocated, 2 lost to followup, 14 analyzed B: 6 allocated, 2 lost to followup, 6 analyzed	Integrative Care (IC) (acupuncture, chiropractic, internal med consult, massage, occupational therapy, physical therapy, mind-body techniques, neuro consult, nutrition counseling, ortho consult, psych and rheum consult as needed) + usual care (A) vs. Usual care (medical care) 12 weeks	Mean Age: 47 vs. 48 Female: 50% vs. 67% Average Pain (0-10): 4.8 vs. 5.7 Modified RMDQ: 15.7 vs. 16	NR	Pain RMDQ SF-12 worry difficulty with activities

Appendix E31. Data Abstraction of Randomized Controlled Trials of Multidisciplinary Rehabilitation

Author, Year	Duration of Followup	Results	Adverse Events Including Withdrawals	Funding Source	Quality Rating
Eisenberg, 2012	2, 5, 12, and 26 weeks	RMDQ mean differences, A vs. B Week 2: 12 vs. 11.3 (p=0.87) Week 5: 8.5 vs. 13 (p=0.26) Week 12: 3.9 vs. 11 (p=0.08) Week 26: 4.3 vs. 10.7 (p=0.10) Pain (0-10 scale) Week 2: 3.6 vs. 4.8 (p=0.62) Week 5: 1.9 vs. 5.5 (p=0.05) Week 12: 0.6 vs. 5.0 (p=0.005) Week 26: 1.0 vs. 4.7 (p=0.04) SF-12 physical Week 2: 35 vs. 41 (p=0.90) Week 5: 42 vs. 42 (p=0.38) Week 12: 49 vs 43 (p=0.06) Week 26: 51 vs. 44 (p=0.03) SF-12 mental Week 2: 47 vs. 51 (p=0.26) Week 5: 51 vs. 50 (p=0.59) Week 12: 501 vs 51 (p=0.48) Week 26: 54 vs. 51 (p=1.00) Days in bed, days at home and reduced activity days NS Regression showed positive differences significant for RMDQ, pain, and bothersomness at 12 weeks, but not at 26 weeks	1 pain at acupuncture site	NIH NCAM and Bernard Osher Foundation	

Appendix E31. Data Abstraction of Randomized Controlled Trials of Multidisciplinary Rehabilitation

Author, Year	Country Number of Centers and Setting	Inclusion Criteria	Number Randomized, Analyzed Attrition	Intervention	Study Participants	Duration of Pain (acute, subacute, chronic)	Outcome Measures
Gatchel, 2003	USA, Texas, single center	LBP >10 weeks since work injury Aged 18-65 No history of chronic LBP No need for surgery constant daily pain Work disability Excluded: cancer, fibromyalgia, DSM-IV axis 1 diagnosis, psychosis or suicidal ideation	Randomized 22 early intervention 48 nonintervention Analyzed: 70 Attrition: NR	(A) Intensive Multidisciplinary rehabilitation (physician evaluation, psychology, physical therapy, biofeedback, case management, occupational therapy) vs (B) usual care	Mean Age 38 Female 35% Comparison of groups NR	Subacute (3.8 weeks since original injury)	Pain (Characteristic Pain Inventory) Return to work Disability Days Medication use cost

Appendix E31. Data Abstraction of Randomized Controlled Trials of Multidisciplinary Rehabilitation

Author, Year	Duration of Followup	Results	Adverse Events Including Withdrawals	Funding Source	Quality Rating
Gatchel, 2003	3,6,9,12 months	A vs B Return to work at 12 months: 91% vs 69%, OR 4.55 (p=0.027) Average number of disability days due to back pain: 38 vs 102, p=0.001 Average self-rated pain over last 3 months: 27 vs 43, p=0.001 Taking opioid analgesics: 27% vs 44%, OR 0.44, p=0.020 Cost: $12,721 vs $21,843, p<0.05	NR	National Institute of Mental Health	

Please see Appendix C. Included Studies for full study references.

Appendix E32. Trials of Acupuncture Included in the APS/ACP Review

Author, Year, Title	Purpose of Study	Study Design	Inclusion Criteria	Exclusion Criteria	Number of Treatment and Control Subjects (number approached, number eligible, number enrolled)
Brinkhaus, 2006 Acupuncture in patients with chronic low back pain	Evaluate efficacy of acupuncture versus sham acupuncture or wait list control for chronic low back pain	RCT	Chronic low back pain >6 months, age 40 to 75 years, average pain intensity at least 40 on a 100 point scale in the last 7 days, only non-steroidal anti-inflammatory drugs in last 4 weeks	Protrusion or prolapse of 1 or more intervertebral discs with concurrent neurological symptoms; radicular pain; prior vertebral column surgery; infectious spondylopathy; low back pain caused by inflammatory, malignant, or autoimmune disease; significant congenital deformation of the spine; compression fracture; spinal stenosis; spondylolysis or spondylolisthesis; patients with Chinese medicine diagnoses warranting treatment with moxibustion; acupuncture during the past 12 months	2250 approached Number eligible not reported 301 randomized (142 to acupuncture, 75 to sham acupuncture, 79 to waiting list)

Appendix E32. Trials of Acupuncture Included in the APS/ACP Review

Author, Year, Title	Subject Age, Gender, Diagnosis	Country and Setting	Sponsor	Measures
Brinkhaus, 2006 Acupuncture in patients with chronic low back pain	Mean age: 59 vs. 58 vs. 59 years Female gender: 64% vs. 75% vs. 68% Non-white race: Not reported Duration of low back pain: 14.7 vs. 13.6 vs. 15.8 years Pain (0 to 100 scale): 63 vs. 67 vs. 66	Germany Multicenter Acupuncture clinics	Sponsored by a variety of German social health insurance funds	Pain intensity: 0 to 100 Back function: German Funktionsfragebogen Hannover-Rucken Global assessment of effects Pain Disability Index (German version) German depression scale (Allgemeine Depressionsskala) SF-36 physical health, mental health, and pain subscales

Appendix E32. Trials of Acupuncture Included in the APS/ACP Review

Author, Year, Title	Type of Intervention	Results	Duration of Followup
Brinkhaus, 2006 Acupuncture in patients with chronic low back pain	A: Acupuncture at least 4 local points and 2 distant points, otherwise semistandardized; 12 session of 30 minutes over 8 weeks B: Sham acupuncture at least 6 of 10 predefined nonacupuncture points C: Wait list control	Acupuncture vs. sham acupuncture vs. wait list control at 8 weeks; acupuncture vs. sham acupuncture at 52 weeks Pain intensity (difference from baseline, 0 to 100 scale): 28.7 vs. 23.6 vs. 6.9 at 8 weeks (p=0.26 for acupuncture vs. sham; p<0.001 for acupuncture vs. wait list control); 39.2 vs. 44.9 at 52 weeks (p=0.20) Back function (mean, 0 to 100 German scale): 66.8 vs. 62.9 vs. 57.7 at 8 weeks, 66.0 vs. 63.1 at 52 weeks (NS) Pain Disability Index (mean, 0 to 100 scale): 18.8 vs. 21.5 vs. 27.1 at 8 weeks, 19.0 vs. 23.0 at 52 weeks (NS) SF-36 physical health scale: 40.5 vs. 36.2 vs. 33.9 at 8 weeks (p=0.004 for acupuncture vs. sham and p<0.001 for acupuncture vs. wait list control); 38.9 vs. 36.1 at 52 weeks (p=0.07) SF-36 mental health scale: No differences at 8 weeks, 50.5 vs. 47.2 at 52 weeks (p=0.04) SF-36 pain scale: 58.8 vs. 50.7 vs. 39.9 at 8 weeks (p=0.01 for acupuncture vs. sham), 52.4 vs. 44.0 at 52 weeks Depression: No significant differences	52 weeks

Appendix E32. Trials of Acupuncture Included in the APS/ACP Review

Author, Year, Title	Loss to Followup	Compliance to Treatment	Adverse Events and Withdrawals Due To Adverse Events	Quality Rating	Comments
Brinkhaus, 2006 Acupuncture in patients with chronic low back pain	19/301	81.2% per-protocol	Acupuncture vs. sham acupuncture vs. wait list control Serious adverse event: 13/140 (9%) vs. 4/70 (6%) vs. 5/74 (8%) Any adverse event:15/140 (11%) vs. 12/70 (17%)		

Appendix E32. Trials of Acupuncture Included in the APS/ACP Review

Author, Year, Title	Purpose of Study	Study Design	Inclusion Criteria	Exclusion Criteria	Number of Treatment and Control Subjects (number approached, number eligible, number enrolled)
Haake, 2007 German acupuncture trials (GERAC) for chronic low back pain	Evaluate efficacy of acupuncture versus sham acupuncture and conventional therapy for chronic low back pain	RCT	Age >18, chronic low back pain >6 months, mean Von Korff Chronic Pain Grade 1 or higher, Hanover Functional Ability Questionnaire score <70%, no previous acupuncture	Previous spinal surgery, previous spinal fractures, infectious or tumors spondylopathy, chronic pain caused by other diseases	1802 approached 575 did not meet inclusion criteria 1162 randomized (387 to verum acupuncture, 387 to sham acupuncture, 388 to conventional therapy)

Appendix E32. Trials of Acupuncture Included in the APS/ACP Review

Author, Year, Title	Subject Age, Gender, Diagnosis	Country and Setting	Sponsor	Measures
Haake, 2007 German acupuncture trials (GERAC) for chronic low back pain	Mean age: 50 vs. 49 vs. 51 years Female gender: 57% vs. 64% vs. 58% Non-white race: Not reported Pain (CPGS): 68 vs. 68 vs. 68 Duration of back pain (years): 8.1 vs. 7.7 vs. 8.1	Germany Multicenter Physician-acupuncturist clinics	Various German public health insurance companies	Treatment response: >=33% improvement or better on 3 pain - related outcomes on the Von Korff Chronic Pain Grade Scale or >=12% improvement on Hanover Functional Ability Questionnaire, did not use other treatments other than permitted rescue medications, and remained blinded SF-36 Patient global assessment: 1 (very good) to 6 (fail) Medication use Adverse events

Appendix E32. Trials of Acupuncture Included in the APS/ACP Review

Author, Year, Title	Type of Intervention	Results	Duration of Followup
Haake, 2007 German acupuncture trials (GERAC) for chronic low back pain	A: Verum acupuncture: 2 30-minute sessions per week, 10 sessions with up to 5 additional sessions B: Sham acupuncture: 2 30-minute sessions per week, 10 sessions with up to 5 additional sessions C: Conventional therapy: No acupuncture, treatment according to German treatment guidelines including 10 sessions with a physician or physiotherapist	Verum acupuncture versus sham acupuncture versus conventional therapy Treatment response (>=33% improvement or better on 3 pain -related outcomes on the Von Korff Chronic Pain Grade Scale or >=12% improvement on Hanover Functional Ability Questionnaire, did not use other treatments other than permitted rescue medications, and remained blinded): 47.6% (184/387) vs. 44.2% (171/387) vs. 27.4% (106/387) (p<0.001 for verum or sham acupuncture versus conventional therapy; p=0.39 for verum versus sham acupuncture) Von Korff Chronic Pain Grade Scale >=33% improvement on 3 pain-related items: 59% vs. 51% vs. 34% Hanover Functional Ability Questionnaire >=12% improvement: 73% vs. 65% vs. 50% Pain, Chronic Pain Grade Scale (0 to 100): 40 vs. 43 vs. 52 SF-12 physical score: 42 vs. 40 vs. 36 SF-12 mental score: 51 vs. 51 vs. 49 Patient global assessment (1 to 6 scale): 2.8 vs. 3.0 vs. 3.5	6 months

Appendix E32. Trials of Acupuncture Included in the APS/ACP Review

Author, Year, Title	Loss to Followup	Compliance to Treatment	Adverse Events and Withdrawals Due To Adverse Events	Quality Rating	Comments
Haake, 2007 German acupuncture trials (GERAC) for chronic low back pain	9% vs. 10% vs. 13% withdrawal	Mean number of sessions: 12.5 vs. 11.9 vs. 10.5	Verum acupuncture versus sham acupuncture versus conventional therapy Serious adverse events: 12 vs. 12 vs. 16 (p=NS) Overall adverse events: 26% (p=0.81 for differences between groups)		

Appendix E32. Trials of Acupuncture Included in the APS/ACP Review

Author, Year, Title	Purpose of Study	Study Design	Inclusion Criteria	Exclusion Criteria	Number of Treatment and Control Subjects (number approached, number eligible, number enrolled)
Thomas, 2006 Randomized controlled trial of a short course of traditional acupuncture compared with usual care for persistent non-specific low back pain	Evaluate whether access to traditional acupuncture care is associated with improved long-term pain relief at equal or less cost compared to usual care	Pragmatic RCT	Age 20 to 65 with LBP, suitable for primary care management according to guidelines, current episode 4 weeks to 12 months in duration	Possible spinal pathology (e.g. carcinoma), severe or progressive motor weakness or central disc prolapse, past spinal surgery, pending litigation, bleeding disorders, currently receiving acupuncture	289 approached 269 eligible 241 randomized (160 to acupuncture offered and 81 to usual general practice management)
Witt, 2006 Pragmatic randomized trial evaluating the clinical and economic effectiveness of acupuncture for chronic low back pain	Evaluate efficacy, safety, and cost-effectiveness of acupuncture for chronic low back pain	Pragmatic RCT	Age >18 years, low back pain >6 months	Prolapsed intervertebral disc, prior spinal surgery, spine infection, low back pain caused by inflammatory, malignant, or autoimmune disease, significant congenital deformity of spine, compression fracture due to osteoporosis, spinal stenosis, spondylolysis or spondylilolisthesis	Number approached not reported 11,630 eligible 3093 randomized 2841 consented (1451 acupuncture, 1390 no acupuncture)

Appendix E32. Trials of Acupuncture Included in the APS/ACP Review

Author, Year, Title	Subject Age, Gender, Diagnosis	Country and Setting	Sponsor	Measures
Thomas, 2006 Randomized controlled trial of a short course of traditional acupuncture compared with usual care for persistent non-specific low back pain	Mean age: 42 vs. 44 years Female gender: 62% vs. 58% Non-white race: 0% vs. 2.5% Duration of back pain: 17.1 vs. 16.7 weeks Back pain extremely bothersome in last week: 56% vs. 56% Believe acupuncture will help back pain: 70% vs. 64%	UK Multicenter General practice clinics	National Health Services Research and Development Health Technology Assessment Programme	Bodily Pain dimension of the General Health Status Profile SF-36 Present Pain Intensity scale of the McGill Pain Questionnaire Oswestrsy Pain Disability Questionnaire SF-36 SF-6D: a preference based single index measure derived from the SF-36 Euro-QOL 5D (EQ-5D): Quality of life measure used for economic analysis Satisfaction with care: 5 point scale, 1 (very satisfied) to 5 (very dissatisfied) Resource use
Witt, 2006 Pragmatic randomized trial evaluating the clinical and economic effectiveness of acupuncture for chronic low back pain	Mean age: 53 vs. 53 years Female gender: 58% vs. 57% Non-white race: Not reported Duration of symptoms: 7.2 vs. 7.2 years Back pain score (0 to 100): 25.5 vs. 25.0	Germany Multicenter Acupuncture clinics	Multiple German social health insurance funds	Back function: Hannover Functional Ability Questionnaire (HFAQ): 0 to 100 scale Low Back Pain Rating Scale: 0 to 100 scale SF-36

Appendix E32. Trials of Acupuncture Included in the APS/ACP Review

Author, Year, Title	Type of Intervention	Results	Duration of Followup
Thomas, 2006 Randomized controlled trial of a short course of traditional acupuncture compared with usual care for persistent non-specific low back pain	A: Offer of acupuncture with up to 10 treatments as soon as feasible if chosen by patient plus usual care B: Usual care by a general practitioner only	Acupuncture offered vs. usual care Mean SF-36 Pain score, mean adjusted difference: +5.1 at 3 months (p=0.129), +5.6 at 12 months (p=0.111), +8.0 at 24 months (p=0.032) Other SF-36 dimensions: No differences McGill Present Pain Intensity, estimated effect (negative favors acupuncture): -0.34 at 3 months (p=0.02), no significant difference at 12 or 24 months Oswestry, estimated effect (negative favors acupuncture): No difference at 3, 12 or 24 months Pain free in past 12 months: 18% vs. 8% (p=0.06) Use of low back pain medication in past 4 weeks: 60% vs. 41% (p=0.03) Satisfaction (proportion very satisfied): 32% vs. 31% for information received (NS), 44% vs. 26% for treatment received (p=0.01), and 37% vs. 25% for overall care received (p=0.04) Incremental cost-effectiveness: 4241 pounds (95% CI 191 to 28,026 pounds) Much less or less worried about low back pain: 60% vs. 38%	24 months
Witt, 2006 Pragmatic randomized trial evaluating the clinical and economic effectiveness of acupuncture for chronic low back pain	A: Acupuncture, maximum 15 sessions, number of acupuncture points and needles at discretion of physician B: No acupuncture	Acupuncture vs. no acupuncture (difference in change from baseline, positive values favor acupuncture) Back function loss (Hannover Functional Assessment Questionnaire, 0 to 100 scale): 22.0 (95% CI 19.3 to 24.7) at 3 months, 3.7 (95% CI 0.7 to 6.7) at 6 months Low Back Pain Rating Scale (0 to 100): 27.2 (95% CI 20.9 to 24.5) at 3 months, 2.7 (95% CI -0.3 t0 5.7) at 6 months SF-36 Physical Component score: 4.7 (95% CI 4.0 to 5.4) at 3 months, 0.6 (95% CI -0.2 to 1.3) at 6 months SF-36 Mental Component score: 2.1 (95% CI 1.4 to 2.8) at 3 months, 0.2 (95% CI -0.6 to 1.0) at 6 months	6 months

Appendix E32. Trials of Acupuncture Included in the APS/ACP Review

Author, Year, Title	Loss to Followup	Compliance to Treatment	Adverse Events and Withdrawals Due To Adverse Events	Quality Rating	Comments
Thomas, 2006 Randomized controlled trial of a short course of traditional acupuncture compared with usual care for persistent non-specific low back pain	24/241 at 12 months, 57/241 at 24 months	150 patients offered acupuncture received it; average 8.1 treatments per patient. 8 patients in usual care group received adjunctive acupuncture from physical therapist in first 3 months. Other treatments similar between groups.	Acupuncture group No events resulting in hospitalization and/or permanent disability or death reported Temporary worsening of symptoms: 63%, 52% moderate or severe Withdrawals due to adverse events: Not reported		No heterogeneity related to acupuncturist; no clear effect of prior beliefs on outcomes
Witt, 2006 Pragmatic randomized trial evaluating the clinical and economic effectiveness of acupuncture for chronic low back pain	7.7% at 3 months	5% of acupuncture patients received fewer than 5 treatments	Acupuncture group 6% reported side effects (54% minor local bleeding or hematoma, 17% pain, 8% 'vegetative symptoms', 21% other)		Cost-effectiveness 10,526 euros/QALY

Please see Appendix C. Included Studies for full study references.

Appendix E33. Data Abstraction of Systematic Reviews of Acupuncture

Author, Year	Comparison	Data Sources	Number and Type of Studies	Interventions and Number of Patients	Methods for Rating Methodological Quality of Primary Studies
Lee, 2013	Acupuncture (as a single treatment, needle only) vs. sham, usual care, nothing	the Cochrane Central Register of Controlled Trials(CENTRAL), Ovid Medline, Embase (1980 to July 2011),and Chinese databases of the China Academic Journal, 4 related Korean journals, trial registries	11 RCTs, Acute LBP (<12 weeks), 1139 patients (approximately 50 per arm), 5 LRoB	A. Acupuncture vs. sham (n=3) B. Acupuncture vs. conventional treatment (i.e. Meds) (n=7) C. Acupuncture + meds vs. meds alone (n=1)	Cochrane, 2009

Appendix E33. Data Abstraction of Systematic Reviews of Acupuncture

Author, Year	Methods for Synthesizing Results of Primary Studies	Results	Adverse Events
Lee, 2013	n=11 qualitative, n=7 meta analysis; Random effects model; heterogeneity assessed using I2 statistic;	A. acupuncture vs. sham: 2 studies; VAS for acute pain, MD 9.38; 95% CI: 17.00, 1.76; P=0.02 - no effects for subacute pain or function B. Acupuncture vs NSAIDs Global assessment: (5 studies; pooled RR, 1.11; 95% CI: 1.06, 1.16; P<0.00001)	Only 2 studies reported: 16 pts reported GI problems at 1 week, 12 at 2 weeks; 4 with changes in energy at 1 week, mild bleeding at site in 3 patients,

Appendix E33. Data Abstraction of Systematic Reviews of Acupuncture

Author, Year	Comparison	Data Sources	Number and Type of Studies	Interventions and Number of Patients	Methods for Rating Methodological Quality of Primary Studies
Lam, 2013	(A) acupuncture versus no treatment, (B) acupuncture versus medication, (C) acupuncture versus TENS, (D) acupuncture versus sham acupuncture, (E) acupuncture in addition to usual care versus self-care or usual care, and (F) electroacupuncture versus usual care.	PubMed, EMBASE, AMED, CINAHL ScienceDirect, CENTRAL, and Cochrane Library	32 studies SR, 25 meta; Chronic LBP, 7 LRoB, 0-48 months follow up	A. acupuncture versus no treatment (n=5) B. acupuncture versus medication (n=3), C. acupuncture versus TENS, (n=3 studies, 122 patients) D. acupuncture versus sham (n=4) acupuncture, E. acupuncture in addition to usual care versus self-care or usual care, (n=4) and F. electroacupuncture versus usual care.(n=6)	Cochrane, 2011

Appendix E33. Data Abstraction of Systematic Reviews of Acupuncture

Author, Year	Methods for Synthesizing Results of Primary Studies	Results	Adverse Events
Lam, 2013	n=32 qualitative; n=25 meta analysis; Statistical heterogeneity was measured using the I 2 statistic, Fixed effects model used below the 50% cut off for I2 statistic, used clinical cutoffs for pain and function to determine clinical significance	A.Pain, mean between-group difference (95% CI): - Immediate post-intervention: (5 studies) − 0.72 [− 0.94 to − 0.49] Function, mean between-group difference (95% CI): Immediate post-intervention: (5 studies) − 0.94 [− 1.41 to − 0.47] B. Pain, mean between-group difference (95% CI): -Immediate post-intervention: (3 studies) − 10.56 [− 20.34 to − 0.78] Function, mean between-group difference (95% CI): - Immediate post-intervention: (3 studies) − 0.36 [− 0.67 to − 0.04] C. Pain immediate post-intervention: (3 studies) "no significant difference" Pain 10-12 week follow-up (2 studies): "no significant difference" Function not reported D. Pain, mean between-group difference (95% CI): -Immediate post-intervention: (4 studies) − 16.76[− 33.33 to − 0.19] -6-12 weeks: (3 studies) − 9.55 [− 16.52 to − 2.58] Function (3 studies) "no differences" E. Pain, mean between-group difference (95% CI) -Immediate post-intervention: (4 studies) −13.99 [−20.48 to − 7.50] -6-12 weeks: (4 studies) −12.91 [− 21.97 to − 3.85] Function: mean between-group difference (95% CI) -Immediate post-intervention: (4 studies) − 0.87 [− 1.61 to − 0 -6-12 weeks: (4 studies) − 0.51 [− 0.91 to − 0.12] F. Pain, mean between-group difference (95% CI): -Immediate post-intervention: (5 studies) − 1.39 [− 2.37 to − 0.40 -6-12 weeks: (4 studies) − 0.66 [− 1.17 to − 0.15] function: not examined	NR

Please see Appendix C. Included Studies for full study references.

Appendix E34. Data Abstraction of Randomized Controlled Trials of Acupuncture

Author, Year	Country Number of Centers and Setting	Inclusion Criteria	Number Randomized, Analyzed Attrition	Intervention	Study Participants	Duration of Pain (acute, subacute, chronic)
Hasegawa, 2014	Brazil, 1 site	Inclusion criteria: 18–65 years seeking medical assistance for ANLBP, defined as pain and discomfort localized below the costal margin and above the inferior gluteal folds for a period of less than 30 days and unrelated to any specific anetiological factors with a score of 4–8 cm on the pain scale (0–10 cm), Exclusion criteria: secondary diagnosis such as spondyloarthropathy, infection, tumeur or fracture, complete scatologia, previous surgery on the spinal column, litigation, who had changed physical activity or undergone acupuncture or physical therapy in the previous 3 months, had previously undergone scalp acupuncture or who were pregnant or had a contraindication to anti-inflammatory drugs	Randomized: 80 Analyzed: 80 Attrition: 0% (0/80)	A. Scalp acupuncture +diclofenac (n=40) B. Sham scalp acupuncture +diclofenac (n=40)	A vs B Mean age 47 vs 44 years 63% vs 65% female 63% vs 55% Caucasian Pain, VAS: 6.6 vs 6.7 Disability, RDQ: 14.9 vs 14.6	Acute: <30 days

Appendix E34. Data Abstraction of Randomized Controlled Trials of Acupuncture

Author, Year	Outcome Measures	Duration of Followup	Results	Adverse Events Including Withdrawal	Funding Source	Quality
Hasegawa, 2014	Pain intensity (VAS scale 0-10; higher score=more pain) RDQ (scale 0-23; higher score=more disability) SF-36 (scale 0-100 for each subscale; higher score=less disability)	Up to 28 days	A vs B: Acute LBP Pain, VAS mean change from baseline: -4.6 vs -3.3; p=0.005 A vs B Disability, RDQ mean change from baseline: -10.8 vs -8.6; p=0.002	No participants experienced AEs	Not reported	Good

Appendix E34. Data Abstraction of Randomized Controlled Trials of Acupuncture

Author, Year	Country Number of Centers and Setting	Inclusion Criteria	Number Randomized, Analyzed Attrition	Intervention	Study Participants	Duration of Pain (acute, subacute, chronic)
Vas, 2012	Spain, 4 centers	Inclusion criteria: new episode (defined as the first such episode in the last 6 months) of nonspecific LBP (defined as pain, muscle tension, or stiffness, localized below the costal margin and above the inferior gluteal folds, with or without referred or radicular leg pain) initiated less than 2 weeks previously, no prior experience of acupuncture treatment, patient's age ranging from 18 to 65 years exclusion: more than 1 absence from work as a result of LBP in the previous 6 months; LBP attributed to recognizable, known specific pathology; generalized dermatopathologies; treatment with dicoumarol anticoagulants; pregnancy	Randomized: 275 Analyzed: 210 Attrition: =23.6% (65/275)	A. True acupuncture (n=68) B. Sham acupuncture (n=68) C. Placebo acupuncture (n=69) D. Control group (n-70)	A vs B vs C vs D Mean age 42 vs 44 vs 44 vs 41 63% vs 57% vs 49% vs 64% female Race not reported (Spain)	Acute: <2 weeks

Appendix E34. Data Abstraction of Randomized Controlled Trials of Acupuncture

Author, Year	Outcome Measures	Duration of Followup	Results	Adverse Events Including Withdrawal	Funding Source	Quality
Vas, 2012	Primary outcome: percentage of people with >35% improvement on the RDQ (0-23 scale) Secondary outcomes: pain intensity (visual analogue scale 0–100 mm), disability (relative change in RMQ), occupational disability due to LBP, persistence of the initial LBP, appearance of new episodes of LBP, and improvement perceived by the patient	48 weeks	A vs B vs C vs D Pain VAS not reported Continuing pain and recurrence of pain reported only A vs B vs C vs D Disability (Proportion achieving 35% improvement in RMQ (0-24) at 3 weeks): 74% vs. 75% vs. 65% vs 44% ($p<0.05$ for A vs C and A vs D)	No serious adverse reaction was recorded in any of the treatment groups. Twelve patients (4.4%) had possible adverse reactions to medication including epigastralgias and nausea, 1 in the TA group, 1 in the SA group, 4 in the PA group, and 6 in the CT group. With respect to adverse effects provoked by all classes of acupuncture treatment, 8 patients (3.9%) reported increased pain after the treatment session, 3 in the TA group, 3 in the SA group, and 2 in the PA group.	Not reported	Good

Appendix E34. Data Abstraction of Randomized Controlled Trials of Acupuncture

Author, Year	Country Number of Centers and Setting	Inclusion Criteria	Number Randomized, Analyzed Attrition	Intervention	Study Participants	Duration of Pain (acute, subacute, chronic)
Yun, 2012	China, 1 hospital	Inclusion criteria: Participant plans to continue enrollment in health plan between 18 and 70 years of age At least one primary care visit for back pain within the past 3–12 months Non-specific, uncomplicated low back pain Exclusion criteria: Previous acupuncture for any reason Low back pain lasting less than three months Mild symptoms [less than 3 on 0–10 pain bothersomeness scale] Specific diseases that could be cause of back pain [metastatic cancer, discitis, herniated disc, vertebral fracture, spinal infection, osteitis condensans, severe or progressive scoliosis, spinal stenosis, spondylolisthesis, ankylosing spondylitis] Complicated back problems [sciatica, back surgery in prior three years]	Randomized: 236 Analyzed: 236 Attrition: =0% (0/236)	A. Back-pain-acupuncture (n=80) B. Standard acupuncture (n=82) C. Usual care (n=74)	A vs B vs C Mean age 33 vs 34 vs 31 33% vs 27% vs 31%female Race not reported (China) Pain, VAS 6.1 vs 6.1 vs. 6.1 Disability, RMDQ: 11.8 vs 12 vs 11.8	Chronic > 3 months

Appendix E34. Data Abstraction of Randomized Controlled Trials of Acupuncture

Author, Year	Outcome Measures	Duration of Followup	Results	Adverse Events Including Withdrawal	Funding Source	Quality
Yun, 2012	Pain intensity (VAS scale 0-10; higher score=more pain) RDQ (scale 0-23; higher score=more disability) SF-36 (scale 0-100 for each subscale; higher score=less disability)	24 weeks	A vs B vs C Pain, bothersomeness (primary) mean change from baseline 24 weeks (0-10 VAS): 2.5 vs. 2.0 vs. 1.2 (p<0.0001) RMDQ mean change from baseline: 6.2 vs. 5.3 vs. 4.1 (p<0.0001)	AEs not reported	Funding not reported	Fair

Appendix E34. Data Abstraction of Randomized Controlled Trials of Acupuncture

Author, Year	Country Number of Centers and Setting	Inclusion Criteria	Number Randomized, Analyzed Attrition	Intervention	Study Participants	Duration of Pain (acute, subacute, chronic)
Weiss, 2013	Germany, 1 hospital	Inclusion criteria: CLBP of 6+ months and age 25–75 years. Exclusion criteria: contraindications to acupuncture, such as anticoagulation with phenprocoumon or warfarin; coagulation disorders or thrombocytopenia (platelet count < 150,000 cells/mm3); poor fluency in German language; insufficient adherence; recent surgical treatment; and herniated vertebral discs, either minor herniations of less than 6 months' duration or major herniations of any duration.	Randomized: 160 Analyzed: 143 Attrition: =10.6% (17/160)	A. Acupuncture plus intensive rehab (n=74) B. Intensive inpatient rehab only (n=69)	A vs B Mean age 49.8 vs 51.7 27% vs 39.1% female Race not reported (Germany) Bodily Pain, SF-36 41.2 vs 36.0 Physical function, SF-36 71.2 vs. 69.8	Chronic > 6 months

Appendix E34. Data Abstraction of Randomized Controlled Trials of Acupuncture

Author, Year	Outcome Measures	Duration of Followup	Results	Adverse Events Including Withdrawal	Funding Source	Quality
Weiss, 2013	SF-36 (scale 0-100 for each subscale; higher score=less disability)	3 months	A vs B Bodily pain, SF-36 mean change from baseline to 3 months post treatment 8.3 vs. 3.8 p=0.28 (p<0.05) Bodily pain, SF-36 mean change from baseline to end of treatment 24.5 vs. 22.6 p=0.56 A vs B Physical function, SF-36 mean change from baseline to 3 months post treatment -3.6 vs. -11.8 p=0.0.02 Physical function, SF-36 mean change from baseline to end of treatment 9.8 vs. 6.4 p=0.20	No major adverse events occurred. Minor adverse effects were nausea in 2.7% of patients, dizziness in 13.5%, urgency in 20.3%, and pain at puncture site in 36.5%.	Funding not reported	Poor-Fair

Please see Appendix C. Included Studies for full study references.

Appendix E35. Data Abstraction of Systematic Reviews of Massage

Author, Year	Comparison	Data Sources	Number and Type of Studies	Interventions and Number of Patients	Methods for Rating Methodological Quality of Primary Studies
Furlan, 2010	1) Massage vs. Sham/placebo massage 2) Massage vs.Other medical treatments 3) Massage vs. No treatment 4) compare the addition of massage to other treatments 5) assess the effectiveness of different techniques of massage	MEDLINE, EMBASE, CINAHL from their beginning toMay 2008. We also searched the Cochrane Central Register of Controlled Trials (The Cochrane Library 2006, issue 3), HealthSTAR and Dissertation abstracts up to 2006	13 studies (1596 pts); 5 LRoB	1. Massage vs. Sham/placebo massage (n=2 studies, 111 pts) 2. Massage vs.Other medical treatments 2a) A vs. SMT (n=1, 67 pts) 2b) A vs. exercise (n=1, 47 pts) 2c) A vs relaxation (n=3, 297 pts) 2d) A vs. acupuncture (n=1, 172 pts) 2e) A vs. education (n=1, 168 pts) 2f) A vs. PT (n=2, 275 pts) 3) Massage vs. No treatment (n=0) 4) Compare the addition of massage to other treatments (n=5) 5) assess the effectiveness of different techniques of massage (n=2)	Cochrane Back Group, 20

Appendix E35. Data Abstraction of Systematic Reviews of Massage

Author, Year	Methods for Synthesizing Results of Primary Studies	Results	Adverse Events
Furlan, 2010	qualitative GRADE 2003, Statistical pooling performed for only ?2 studies due to heterogeneity (no other details provided)	1. Pain, mean between-group difference (95% CI): "Short-term followup (1 month) -0.92 (-1.35 to -0.48) Function, mean between-group difference (95% CI): "Short-term follow-up (?1 month) -1.76 (-3.19 to -0.32) 2a) Pain, mean between-group difference (95% CI): Immediate: -0.94 (-1.76 to -0.12) 2b) Pain, mean between-group difference (95% CI): Immediate:0.6 (-10.3 to -0.17) 2b) Function, mean between-group difference (95% CI): Immediate:-3.38 (-5.96 to -0.8) 2c) Pain, mean between-group difference (95% CI): Immediate (2 studies only)-1.27 (-2.46; -0.08) 2d) no pooled data, 1 study 2e) no pooled data, 1 study 2f) Pain, mean between-group difference (95% CI): Immediate: -0.72 (-0.96 to -0.47) Pain, mean between-group difference (95% CI): long-term follow-up it was -0.95 (-1.39 to -0.51) No data No pooled data Thai vs. Swedish (1 study): Pain, mean between-group difference (95% CI), immediate: 0.2, (-0.4 to 0.7) Pain, mean between-group difference,1 month (95% CI): 0.2 (-0.8 to 0.4)	No SAEs; patients reported soreness during or shortly after the treatment. Some patients also reported an allergic reaction (e.g. rash or pimples) to the massage oil.

Please see Appendix C. Included Studies for full study references.

Appendix E36. Data Abstraction of Randomized Controlled Trials of Massage

Author, Year	Country Number of Centers and Setting	Inclusion Criteria	Number Randomized, Analyzed Attrition	Intervention	Study Participants	Duration of Pain (acute, subacute, chronic)
Cho 2013	Korea 3 hospital-based clinics	Age 18-65 years with nonspecific chronic LBP at least 3 months duration, VAS >5 (scale 0-10) and intact on neurological exam. Exclude: Sciatic pain, pain mainly below the knee, serious spinal disorders, vertebral fracture, spinal infection, inflammatory spondylitis, cauda equina compression, history of spinal surgery or scheduled surgery, other acupuncture treatment, severe psychiatric or psychological disorder, history of corticosteroid, narcotic, muscle relaxant or herbal medicine to treat LBP.	Randomized: 130 Analyzed: 116 Attrition: 11% (14/130)	A. Acupuncture 2x/week for 6 weeks (n=57) B. Sham acupuncture with blunt needles (n=59)	A vs B Mean age 42 vs 42 years 82% vs 86% female Race not reported Pain intensity 6.52 vs 6.37 Pain bothersomeness 6.44 vs 6.32 ODI (Korean version) 28.23 vs 24.17 (p=0.04) SF-36 (Korean version) 107.72 vs 110.41 (unclear which subscales were used) BDI (Korean version)11.33 vs 11.75	Chronic: Mean duration not reported; inclusion criteria required ≥3 months duration at study entry

Appendix E36. Data Abstraction of Randomized Controlled Trials of Massage

Author, Year	Outcome Measures	Duration of Followup	Results	Adverse Events Including Withdrawals	Funding Source	Quality
Cho 2013	Pain intensity (VAS scale 0-10; higher score=more pain) Pain bothersomeness (VAS scale 0-10; higher score=more bothersomeness) ODI (scale 0-100; higher score=more disability) SF-36 (scale 0-100 for each subscale; higher score=less disability) BDI (scale 0-63; higher score=greater depression)	6 months	A vs B <u>8-week outcomes (primary endpoint)</u> Pain intensity: 3.00 (SD 2.41) vs 4.10 (SD 1.85); p=0.007; mean change from baseline 0.53 (SD 0.39) vs 0.35 (SD 0.29); p=0.007 Pain bothersomeness: 3.08 (SD 2.44) vs 4.05 SD 1.84); p=0.02; mean change from baseline 0.53 (SD 0.34) vs 0.35 (SD 0.30); p=0.003 ODI, mean change from baseline: 0.42 (SD 0.39) vs 0.29 (SD 0.44); p=0.10 SF-36, mean change from baseline: 0.20 (SD 0.23) vs 0.16 (SD 0.13); p=0.006 BDI, mean change from baseline: 0.39 (SD 0.56) vs 0.26 (SD 0.83); p=0.34 <u>6-month outcomes</u> Pain intensity: 2.79 (SD 2.44) vs 3.52 (SD 2.53); p=0.11; mean change from baseline 0.56 (SD 0.41) vs 0.44 (SD 0.41); p=0.12 Pain bothersomeness: 2.85 (SD 2.44) vs 3.63 SD 2.37); p=0.08; mean change from baseline 0.56 (SD 0.38) vs 0.41 (SD 0.39); p=0.04 ODI, mean change from baseline: 0.44 (SD 0.38) vs 0.24 (SD 1.10); p=0.20 SF-36, mean change from baseline: 0.20 (SD 0.23) vs 0.14 (SD 0.15); p=0.09 BDI, mean change from baseline: 0.44 (SD 0.58) vs 0.36 (SD 0.66); p=0.49	A vs B Withdrawals: 11% (7/65) vs 11% (7/65); RR 1.00 (95% CI 0.37 to 2.69) Withdrawals due to AEs: Not reported Serious AEs: None in either group Any AE: 15% (10/65) vs 26% (17/65); RR 0.59 (95% CI 0.29 to 1.19) Pain at acupuncture site: 3% (2/65) vs 3% (2/65); RR 1.00 (95% CI 0.15 to 6.89) Bruise at acupuncture site: 2% (1/65) vs 0% (0/65); RR 3.00 (95% CI 0.12 to 72) Worsened LBP: 6% (4/65) vs 12% (8/65); RR 0.50 (95% CI 0.16 to 1.58)	Not reported	Good

Appendix E36. Data Abstraction of Randomized Controlled Trials of Massage

Author, Year	Country Number of Centers and Setting	Inclusion Criteria	Number Randomized, Analyzed Attrition	Intervention	Study Participants	Duration of Pain (acute, subacute, chronic)
Cherkin, 2011	USA, 1 site (Group Health)	Inclusion criteria: LBP 3+ months without 2 or more pain-free weeks and pain bothersomeness rated at least 3 on a scale of 0 to 10 Exclusion criteria: specific causes of back pain, sciatica, back surgery in the past 3 years, or medicolegal issues, conditions making treatment difficult	Randomized: 402 Analyzed: 366 Attrition: 8.9% (36/402)	A. Structural massage (n=132) B. Relaxation massage (n=136) C. Usual care (n=133)	A vs B vs C 46 vs 47 vs 48 Mean age 66% vs 65% vs 62% female 86% vs 87% vs 86% white LBP Bothersomeness, VAS: 5.6 vs 5.6 vs 5.8 Disability, RDQ: 10.1 vs 11.6 vs 10.5	> 6 weeks

Appendix E36. Data Abstraction of Randomized Controlled Trials of Massage

Author, Year	Outcome Measures	Duration of Followup	Results	Adverse Events Including Withdrawals	Funding Source	Quality
Cherkin, 2011	Pain intensity (VAS scale 0-10; higher score=more pain) Pain bothersomeness (VAS scale 0-10; higher score=more bothersomeness) Pain intensity (VAS scale 0-10; higher score=more pain) SF-36 (scale 0-100 for each subscale; higher score=less disability) BDI (scale 0-63; higher score=greater depression)	52 weeks	A vs B:LBP bothersomeness, VAS mean change from baseline (10 weeks):A vs C: –1.4 (–1.9 to –0.8) B vs C: –1.7 (–2.2 to –1.2)A vs B: 0.3 (–0.2 to 0.8) P<0.05 but not reported separately Disability, RDQ mean change from baseline (10 weeks): A vs C: –2.5 (–3.5 to –1.4) B vs C: –2.9 (–4.0 to –1.8) A vs B: 0.5 (–0.5 to 1.5) P<0.05 but not reported separately	Five of 134 (4%) relaxation massage recipients and 9 of 131 (7%) structural massage recipients reported adverse events possibly related to massage, mostly increased pain.	NCCAM	Good

Appendix E36. Data Abstraction of Randomized Controlled Trials of Massage

Author, Year	Country Number of Centers and Setting	Inclusion Criteria	Number Randomized, Analyzed Attrition	Intervention	Study Participants	Duration of Pain (acute, subacute, chronic)
Kong, 2012	China, 1 site	Inclusion criteria: 15–35 years old; nonspecific low back pain without any relevant ongoing pathologies such as disc prolapse, fractures, spondylolisthesis, tumor, osteoporosis, or infection Exclusion criteria: other pain syndromes; spinal surgery in the past 6 months or having to undergo surgery or invasive examinations during the study; neurological disease; psychiatric disease; serious chronic disease that could interfere with the outcomes, pregnant or planning to become pregnant during the study	Randomized: 110 Analyzed: 101 Attrition: =8.1% (9/110)	A: Chinese massage with herbal ointment (n=55) B: Standard massage (n=55)	A vs B Mean age 21 vs 20 (male athletes) 26/55 vs 27/55 female Race not reported (Shanghai) Pain, 5.4 vs. 5.4 Disability, not reported	Acute (duration not specified)

Appendix E36. Data Abstraction of Randomized Controlled Trials of Massage

Author, Year	Outcome Measures	Duration of Followup	Results	Adverse Events Including Withdrawals	Funding Source	Quality
Kong, 2012	Primary outcome: change in pain by the Chinese Short Form McGill Pain Questionnaire (CSFMPQ). The C-SFMPQ also includes a visual analogue scale (VAS, rang 0 to 10, with higher scores indicating greater pain)	1 month and 3 months	A vs B Immediately after treatment: Pain mean change from baseline (0-10 VAS): (− 0.64 points [95% CI, − 1.04 to − 0.24]; P = 0. 002 Disability not reported C-SFMPQ scores favored A vs B Outcomes at 1 month post treatment: VAS scores (−0.66 points [95% CI, −1.13 to −0.19]; P = 0.007).	No AEs occurred, no people withdrew	National Natural Science Foundation of China	Good

Appendix E36. Data Abstraction of Randomized Controlled Trials of Massage

Author, Year	Country Number of Centers and Setting	Inclusion Criteria	Number Randomized, Analyzed Attrition	Intervention	Study Participants	Duration of Pain (acute, subacute, chronic)
Sritoomma, 2014	Thailand, 1 clinic	Inclusion criteria: aged 60 years and older; able to listen, speak, read and write Thai language; and diagnosed with CLBP by a medical practitioner (lasting for over 12 weeks). Exclusion criteria: skin disease, inflammation or infection on back, a history of back fracture or back surgery, body temperature of more than 38.5 ◦C on the examination day, hemi/paraparesis, infectious diseases (e.g. tuberculosis or AIDS), cancer, prior experience of receiving any type of massage in the three months before this study.	Randomized: 140 Analyzed: 140 Attrition: 0%	A. Swedish massage with ginger oil (n=70) B. Thai massage (n=70)	A vs B Mean age not described (60 and older) 77% vs 83% female Race not described (Thailand) Pain, VAS: 66.66 vs. 63.27 Disability, ODQ: 26.9 vs. 29.5	Chronic

Appendix E36. Data Abstraction of Randomized Controlled Trials of Massage

Author, Year	Outcome Measures	Duration of Followup	Results	Adverse Events Including Withdrawals	Funding Source	Quality
Sritoomma, 2014	Primary outcomes: Pain intensity (VAS scale 0-10; higher score=more pain and McGill Pain Questionnaire) RDQ (scale 0-23; higher score=more disability)	6th and 15th week	A vs B: 15 weeks: Pain, VAS mean change from baseline: −6.37 (−12.58,−0.17) 0.044 ODQ mean difference in change from baseline: −3.66 (−7.17, −0.14) 0.042	AES not reported, no withdrawals reported	Centre for Health Practice Innovation	Fair

Appendix E36. Data Abstraction of Randomized Controlled Trials of Massage

Author, Year	Country Number of Centers and Setting	Inclusion Criteria	Number Randomized, Analyzed Attrition	Intervention	Study Participants	Duration of Pain (acute, subacute, chronic)
Romanowski, 2012	Poland, ? 1 site	Inclusion criteria: age between 60 and 75, the medication had to be stable for at least one month before the study and no intra-articular injections carried out during previous month. Exclusion criteria: skin diseases, abuse of alcohol, legal or illegal drugs, pregnancy, hemophilia, arteriosclerotic diseases, including ischemic heart disease or myocardial infarction, diseases that call for anticoagulating therapy, skin diseases.	Randomized: 26 Analyzed: 26 Attrition: 0%	A. Therapeutic massage (n=13) B. Deep tissue massage (n=13)	A vs B Not described except to say there were no differences in age and gender	Chronic
Zheng, 2012	China	Inclusion criteria: non-specific low back pain lasting more than 3 months and an age of 21 to 75 years. Exclusion criteria: language barriers and those with low back pain caused by neoplasm, osteoporosis, vertebral fracture, rheumatoid arthritis, acute herniated disc accompanied by nerve root entrapment, and unstable spondylolisthesis.	Randomized: 64 Analyzed: 62 Attrition: =3.1% (2/64)	A. Massage + traction (n=32) B. Traction alone (n=32)	A vs B 14/32 vs. 15/30 females 43 vs 42 mean age Pain, function not reported Race not reported (China)	CLBP > 12 weeks

Appendix E36. Data Abstraction of Randomized Controlled Trials of Massage

Author, Year	Outcome Measures	Duration of Followup	Results	Adverse Events Including Withdrawals	Funding Source	Quality
Romanowski, 2012	Pain intensity (VAS scale 0-10; higher score=more pain) ODI (scale 0-100; higher score=more disability) Quebec Back Pain Disability Scale [QBPD]	10 days "after treatment"	A vs B Mean change in VAS: 13.54 ± 7.75 vs. 24.92 ± 13.55 p<0.001 Mean change in ODI: 9.46 ± 11.22 vs. 16.38 ± 11.68 p<0.001	AES not reported, no withdrawals reported	Funding source not described	Poor
Zheng, 2012	Pain intensity (VAS scale 0-10; higher score=more pain), Muscle hardness and muscle tenderness	Immediately after treatment at 3 weeks	A vs B Immediately at end of treatment at 3 weeks?: Mean difference in pain VAS 1.9±0.9 vs. 1.4±0.8 p <0.05	AEs not reported; 2 discontinued due to worsening symptoms, but unclear from which group; 2 withdrew from study, but no reason given and treatment group not described	National Natural Science Foundation of China	Poor

Please see Appendix C. Included Studies for full study references.

Appendix 37. Trials of Spinal Manipulation Included in the APS/ACP Review

Author, Year, Title	Purpose of Study	Study Design	Inclusion Criteria	Exclusion Criteria	Number of Treatment and Control Subjects (number approached, number eligible, number
Hurwitz, 2002 A randomized trial of medical care with and without physical therapy and chiropractic care with and without physical modalities for patients with low back pain: 6-month follow-up outcomes from the UCLA Low Back Pain Study Hurwitz, 2006 A randomized trial of chiropractic and medical care for patients with low back pain. Eighteen-month follow-up outcomes from the UCLA Low Back Pain Study	To evaluate the efficacy of chiropractic care versus medical care for low back pain of unspecified duration	RCT	HMO members, low back pain with or without leg pain, no treatment within previous month, at least 18 years old	Low back pain related to fracture, tumor, infection, spondyloarthropathy, or other nonmechanical cause; treated by electrical devices (such as a pacemaker); blood coagulation disorder or using corticosteroids or anticoagulants; progressive, unilateral lower limb muscle weakness; current symptoms or signs of cauda equina syndrome; plans to move out of the area; not accessible by phone; unable to read English	2,355 approached 1,469 eligible 681 enrolled (169 chiropractic care only, 172 chiropractic care plus physical modalities, 170 medical care only, 170 medical care + physical therapy)
Santilli, 2006 Chiropractic manipulation in the treatment of acute back pain and sciatica with disc protrusion: a randomized double-blind clinical trial of active and simulated spinal manipulations	To evaluate the efficacy of spinal manipulation in patients with lumbar disc herniation and sciatica	RCT	Acute (<10 days) low back pain at least 5 on a 10 point scale, MRI evidence of disc protrusion, radiating pain elicited by straight leg raise and Wasserman tests	Body mass index >30, lumbar scoliosis >20 degrees, lower limb length difference >1.5 cm, spondylolisthesis, previous spinal surgery, diabetic neuropathy, severe osteoporosis, conditions requiring surgery, herniated disc classified as 4B or 4C, history for chronic low back pain, prior spinal manipulation	485 approached Number eligible not reported 102 randomized (53 to manipulation, 49 to simulated manipulation)

Appendix 37. Trials of Spinal Manipulation Included in the APS/ACP Review

Author, Year, Title	Subject Age, Gender, Diagnosis	Country and Setting	Sponsor	Measures
Hurwitz, 2002 A randomized trial of medical care with and without physical therapy and chiropractic care with and without physical modalities for patients with low back pain: 6-month follow-up outcomes from the UCLA Low Back Pain Study Hurwitz, 2006 A randomized trial of chiropractic and medical care for patients with low back pain. Eighteen-month follow-up outcomes from the UCLA Low Back Pain Study	Mean age: 52 vs. 53 vs. 49 vs. 49 Female gender: 49% vs. 58% vs. 47% vs. 48% nonwhite race: 38% vs. 34% vs. 40% vs. 46% Duration of low back pain >1 year: 46 % vs. 44% vs. 49% vs. 49% Baseline most severe back pain (0 to 10): 6.5 vs. 6.7 vs. 6.5 vs. 7.0	USA Multicenter Medical, chiropractic, physical therapy clinics	Federal and foundation funds only	Pain: VAS (0 to 10) Roland-Morris Disability Questionnaire (0 to 24)
Santilli, 2006 Chiropractic manipulation in the treatment of acute back pain and sciatica with disc protrusion: a randomized double-blind clinical trial of active and simulated spinal manipulations	Age 50+ years: 28% vs. 35% Female gender: 30% vs. 45% nonwhite race: Not reported Duration of symptoms: all <10 days (be design) Mean pain (0 to 10): 6.4 vs. 6.4	Italy Two centers Rehabilitation clinics	Supported by the two participating institutions and the nonprofit Institution of Rome	Number pain free at 180 days Treatment failure (number of patients stopping treatment due to no benefit) Number of days with pain Number of days with NSAIDs Number of patients with reduction in local or referred pain SF-36

Appendix 37. Trials of Spinal Manipulation Included in the APS/ACP Review

Author, Year, Title	Type of Intervention	Results	Duration of Followup
Hurwitz, 2002 A randomized trial of medical care with and without physical therapy and chiropractic care with and without physical modalities for patients with low back pain: 6-month follow-up outcomes from the UCLA Low Back Pain Study Hurwitz, 2006 A randomized trial of chiropractic and medical care for patients with low back pain. Eighteen-month follow-up outcomes from the UCLA Low Back Pain Study	A: Chiropractic care only at discretion of chiropractor B: Chiropractic care with physical modalities (heat or cold therapy, ultrasound, or EMS) C: Medical care only at discretion of provider (education, analgesics and other medications, recommendations for bed rest and physical activities) D: Medical care with physical therapy (heat therapy, cold therapy, ultrasound, EMS, mobilization, traction, supervised therapeutic exercise, or strengthening and flexibility)	**Chiropractic care vs. medical care (adjusted between-group difference in improvement from baseline)** Most severe pain (0 to 10 scale): -0.25 (95% CI -0.96 to 0.45) at 6 months, -0.64 (95% CI -1.38 to -0.21) at 18 months Average pain (0 to 10 scale): -0.26 (95% CI -0.81 to 0.29) at 6 months, -0.50 (-1.09 to 0.08) at 18 months RDQ score (0 to 24 scale): -0.37 (95% CI -1.63 to 0.90) at 6 months, -0.69 (-2.02 to 0.65) at 18 months **Medical care + physical therapist care vs. medical care alone** Most severe pain: -0.61 (95% CI -1.31 to 0.10) at 6 months, -0.95 (95% CI -1.69 to -0.21) at 18 months Average pain: -0.63 (95% CI -1.19 to -0.08) at 6 months, -0.76 (-1.35 to -0.17) at 18 months RDQ score: -1.78 (95% CI -3.05 to -0.51) at 6 months, -2.11 (95% CI -3.46 to -0.77) at 18 months **Chiropractic care + physical modalities vs. chiropractic care** Most severe pain: -0.15 (95% CI -0.85 to 0.55) at 6 months, +0.25 (-0.49 to 0.98) at 18 months Average pain: -0.26 (95% CI -0.81 to 0.29) at 6 months, +0.12 (-0.46 to 0.71) at 18 months RDQ score: +0.12 (95% CI -1.15 to +1.38) at 6 months, -0.01 (95% CI -1.35 to +1.32) at 18 months	18 months
Santilli, 2006 Chiropractic manipulation in the treatment of acute back pain and sciatica with disc protrusion: a randomized double-blind clinical trial of active and simulated spinal manipulations	A: Manipulation B: Sham manipulation	Manipulation vs. sham manipulation Proportion pain-free (radiating pain) at 180 days: 55% (29/53) vs. 20% (10/49), p<0.0001 Proportion pain-free (local pain) at 180 days: 28% (15/53) vs. 6% (3/49) Use of NSAIDs (days): 1.8 vs. 3.7 days SF-36: No differences Kellner symptom scale: No differences	6 months

Appendix 37. Trials of Spinal Manipulation Included in the APS/ACP Review

Author, Year, Title	Loss to Followup	Compliance to Treatment	Adverse Events and Withdrawals Due To Adverse Events	Quality Rating	Comments
Hurwitz, 2002 A randomized trial of medical care with and without physical therapy and chiropractic care with and without physical modalities for patients with low back pain: 6-month follow-up outcomes from the UCLA Low Back Pain Study Hurwitz, 2006 A randomized trial of chiropractic and medical care for patients with low back pain. Eighteen-month follow-up outcomes from the UCLA Low Back Pain Study	4% at 6 months, 10% at 18 months	98-99% had at least one visit to assigned provider; 32-36% of chiropractic groups and 11-19% of medical care groups saw other type of provider. 68% of patients assigned to medical care + physical therapy had at least one physical therapy visit.	Not assessed		
Santilli, 2006 Chiropractic manipulation in the treatment of acute back pain and sciatica with disc protrusion: a randomized double-blind clinical trial of active and simulated spinal manipulations	2/102	Average number of sessions: 4.8 vs. 4.5	Not reported		

Appendix 37. Trials of Spinal Manipulation Included in the APS/ACP Review

Author, Year, Title	Purpose of Study	Study Design	Inclusion Criteria	Exclusion Criteria	Number of Treatment and Control Subjects (number approached, number eligible, number
UK BEAM Trial team, 2004 United Kingdom back pain exercise and manipulation (UK BEAM) randomized trial: effectiveness of physical treatments for back pain in primary care	To evaluate the efficacy of spinal manipulation, exercise, both, or usual 'best care' in patients with low back pain	RCT	Low back pain with or without radiation mainly above knee, age 18 to 65, score of four or more on Rolad disability questionnaire, pain every day for 28 days before enrollment or for 21 out of 28 days before randomization and 21 out of 28 days before that, agreed to avoid other physical treatments for three months	Possibility of serious spinal disorder, pain below knee, previous spinal surgery, another more troublesome musculoskeletal disorder, previous treatment in pain management clinic, severe psychiatric disorder, another important medical condition, severe hypertension, anticoagulant treatment, long term steroids, unable to walk >100 m when free of back pain, unable to get up and down to floor, physical therapy in last 3 months	7917 approached 4052 eligible 1334 randomized (333 to manipulation + exercise, 353 to manipulation, 310 to exercise, and 338 to usual care)

Appendix 37. Trials of Spinal Manipulation Included in the APS/ACP Review

Author, Year, Title	Subject Age, Gender, Diagnosis	Country and Setting	Sponsor	Measures
UK BEAM Trial team, 2004 United Kingdom back pain exercise and manipulation (UK BEAM) randomized trial: effectiveness of physical treatments for back pain in primary care	Mean age: 43 years Female gender: 56% nonwhite race: 4% Current episode >90 days: 59% Roland disability score: 9.0	UK Multicenter Primary care	Medical Research Council, National Health Service	Roland Disability Questionnaire Von Korff scale Back Beliefs questionnaire Fear Avoidance Beliefs Questionnaire SF-36 EuroQol

Appendix 37. Trials of Spinal Manipulation Included in the APS/ACP Review

Author, Year, Title	Type of Intervention	Results	Duration of Followup
UK BEAM Trial team, 2004 United Kingdom back pain exercise and manipulation (UK BEAM) randomized trial: effectiveness of physical treatments for back pain in primary care	A: Manipulation + exercise B: Manipulation (up to 8 twenty minute sessions over 12 weeks) C: Exercise (individual assessment followed by group classes incorporating cognitive behavioral principles, up to 8 sixty minute sessions over 4 to 8 weeks and a 'refresher' class at 12 weeks) D: Usual care (based on UK national acute back pain guidelines)	Net benefit from manipulation + exercise, manipulation, and exercise vs. usual care alone at 12 months Roland (0 to 24 scale): 1.30 (0.54 to 2.07) vs. 1.01 (0.22 to 1.81) vs. 0.39 (-0.41 to 1.19) Modified Von Korff pain (0 to 100 scale): 6.71 (2.47 to 10.95) vs. 5.87 (1.58 to 10.17) vs. 4.90 (0.30 to 9.50) Modified Von Korff disability (0 to 100 scale): 6.71 (2.62 to 10.80) vs. 5.65 (1.57 to 9.72) vs. 4.56 (0.34 to 8.78) Fear avoidance beliefs questionnaire-physical scale (0 to 24 scale): 1.24 (0.07 to 2.41) vs. -0.10 (-1.09 to 0.89) vs. 1.08 (-0.05 to 2.22) Back beliefs questionnaire (9 to 45 scale): 2.96 (1.84 to 4.07) vs. 1.43 (0.33 to 2.54) vs. 1.46 (0.33 to 2.58) SF-36 physical component (0 to 100): 2.53 (0.96 to 4.09) vs. 1.68 (0.18 to 3.19) vs. 1.55 (-0.02 to 3.11) SF-36 mental component (0 to 100): 1.30 (-0.55 to 3.14) vs. 1.68 (-0.21 to 3.57) vs. 0.34 (-1.69 to 2.37)	12 months

Appendix 37. Trials of Spinal Manipulation Included in the APS/ACP Review

Author, Year, Title	Loss to Followup	Compliance to Treatment	Adverse Events and Withdrawals Due To Adverse Events	Quality Rating	Comments
UK BEAM Trial team, 2004 United Kingdom back pain exercise and manipulation (UK BEAM) randomized trial: effectiveness of physical treatments for back pain in primary care	26% at 1 year, 23% at 3 months	Not clear	"No serious adverse events"		In a cost utility analysis (UK BEAM Trial Team, BMJ 2005, doi:10.1136/bmj.38282.607859.AE), compared top best care in general practice the incremental cost-effectiveness of manipulation + exercise was 3800 pounds/QALY (dominates exercise alone), manipulation alone 4800 pounds/QALY, and exercise alone 8300 pounds/QALY;

Please see Appendix C. Included Studies for full study references.

Appendix E38. Data Abstraction of Systematic Reviews of Spinal Manipulation

Author, Year	Comparison	Data Sources	Number and Type of Studies	Interventions and Number of Patients	Methods for Rating Methodological Quality of Primary Studies
Rubenstein, 2012 - SMT for acute LBP, update of Cochrane review in 2004	1) SMT versus inert interventions; 2) SMT versus sham SMT; 3) SMT versus all other therapies; 4) SMT plus any intervention versus that same intervention alone (i.e. SMT as an adjunct therapy); 5) SMT versus another SMT technique	2000-3/2011: Cochrane Central Register of Controlled Trials, MEDLINE, EMBASE CINAHL, PEDro, Index to Chiropractic Literature	20 RCTs (n=2674); 6 with LRoB, , acute LBP < 6 weeks, 18+ yrs old; outcomes short, intermediate and long term (>12 months)	1) A: SMT versus B: inert interventions (n=7) 2) A: SMT versus B: sham SMT (n=1) 3) A: SMT versus B: all other therapies (n=8) 4) A: SMT plus any intervention versus B: that same intervention alone (n=4) 5) A: SMT versus B: another SMT technique (n=3)	Cochrane Back Group - 2011
Rubenstein, 2012	Spinal manipulation therapy (SMT) vs no SMT or one SMT technique vs another for acute LBP	Cochrane Central Register of Controlled Trials, MEDLINE, EMBASE CINAHL, PEDro, Index to Chiropractic Literature through March 2011	20 RCTs: 9 acute LBP; 4 mixed acute and subacute LBP; 6 any LBP Duration of followup XX to XX	A. Any SMT (n=20) A1. Thrust SMT (n=XX) A2. Non-thrust SMT (n=XX) B. Other active interventions (exercise; physical therapy; massage; standard care; back school; n=8) C. Sham SMT (n=1) D. Intert interventions (education; ultrasound alone; ultrasound + cold; ultrasound; short-wave diathermy; anti-edema gel; bed rest; n=7)	Cochrane Back Group Criteria (2011)

Appendix E38. Data Abstraction of Systematic Reviews of Spinal Manipulation

Author, Year	Methods for Synthesizing Results of Primary Studies	Results	Adverse Events
Rubenstein, 2012 - SMT for acute LBP, update of Cochrane review in 2004		all outcomes- pain, function, QOL, work, global improvement: low to very low quality evidence of no difference in effect of SMT compared to inert interventions, shamSMT, or when added to another intervention, low to mod no diff vs. other interventions, exception: moderate short-term effect of SMT on functional status when added to another intervention (two RCTs, SMD -0.41, 95% CI -0.73 to -0.10	6 studies reported AEs; 1 study 25% had minor AEs, but no difference between groups; 1 study 4 SAEs, but not related
Rubenstein, 2012	n=20 qualitative, GRADE, 2008; meta analysis n=16, Random effects model; heterogeneity assessed using I^2 statistic; funnel plots constructed to test for publication bias; pooled effects assessed for clinical relevance according to predefined cut-offs	A vs A+B, B, C or D Pain, mean between-group difference (95% CI) - -1 week (8 studies): -0.13 (-0.82 to 0.56) -1 month (5 studies): -0.56 (-1.07 to -0.06) -3 to 6 months (3 studies): -0.42 (-1.00 to 0.17) -12 months (1 study): 0.40 (-0.08 to 0.88) Functional status, standardized mean difference (95% CI) - -1 week (6 studies): -0.31 (-0.59 to -0.03) -1 month (9 studies): -0.23 (-0.42 to -0.03) -3 to 6 months (5 studies): -0.26 (-0.49 to -0.02) -12 months (2 studies): 0.06 (-0.14 to 0.25)	

Appendix E38. Data Abstraction of Systematic Reviews of Spinal Manipulation

Author, Year	**Comparison**	Data Sources	Number and Type of Studies	Interventions and Number of Patients	Methods for Rating Methodological Quality of Primary Studies
Rubenstein, 2012 (continued)					
Rubenstein, 2012 (continued)					
Rubenstein, 2012 (continued)					

Appendix E38. Data Abstraction of Systematic Reviews of Spinal Manipulation

Author, Year	Methods for Synthesizing Results of Primary Studies	Results	Adverse Events
Rubenstein, 2012 (continued)		A vs B Pain, mean between-group difference (95% CI) - -1 week (3 studies): 0.06 (-0.53 to 0.65) -1 month (3 studies): -0.15 (-0.49 to 0.18) -3 to 6 months (2 studies): -0.20 (-1.13 to 0.73) -12 months (1 study): 0.40 (-0.08 to 0.88) Functional status, standardized mean difference (95% CI) - -1 week (1 study): 0.07 (-0.18 to 0.33) -1 month (3 studies): -0.11 (-0.26 to 0.05) -3 to 6 months (2 studies): -0.09 (-0.33 to 0.15) -12 months (2 studies): 0.06 (-0.14 to 0.25) Recovery, RR (95% CI) - -1 month (2 studies): 1.06 (0.94 to 1.12) -3 months (1 study): 1.29 (0.96 to 1.74) Return to work, RR (95% CI) - -1 month (1 study): 1.01 (0.91 to 1.12) -6 months (1 study): 1.07 (0.98 to 1.16)	
Rubenstein, 2012 (continued)		A vs C Pain, mean difference (95% CI) - -1 month (1 study): -0.5 (-1.39 to 0.39) Functional status, standardized mean difference (95% CI) - -1 month (1 study): -0.35 (-0.76 to 0.06)	
Rubenstein, 2012 (continued)		A vs D Pain, mean between-group difference (95% CI) - -1 week (3 studies): 0.14 (-0.69 to 0.96) -1 month (1 study): -1.20 (-2.01 to -0.39) -3 months (1 study): -1.20 (-2.11 to -0.29) Functional status, standardized mean difference (95% CI) - -1 week (2 studies): -0.08 (-0.37 to 0.21) -1 month (1 study): -0.27 (-0.58 to 0.04) -3 months (1 study): -0.28 (-0.59 to 0.02) Recovery, RR (95% CI) - -1 week (2 studies): 0.96 (0.50 to 1.85) -1 month (1 study): 0.97 (0.85 to 1.10) -3 months (1 study): 1.00 (0.98 to 1.02)	

Appendix E38. Data Abstraction of Systematic Reviews of Spinal Manipulation

Author, Year	Comparison	Data Sources	Number and Type of Studies	Interventions and Number of Patients	Methods for Rating Methodological Quality of Primary Studies
Rubenstein 2012 (continued)					
Rubenstein 2012 (continued)					
Rubenstein, 2011	1) SMT versus inert interventions 2) SMT versus sham SMT 3) SMT versus all other interventions4) SMT in addition to any intervention versus that intervention	CENTRAL MEDLINE EMBASE, CINAHL, PEDro, Index to Chiropractic Literature through June 2009	26 total studies with wide variety of comparisons, 9 with LRoB, LBP >12 weeks, 18+ years old, outcomes short, intermediate and long term (>12 months)	1) A: SMT versus B: inert interventions (n=4) 2) A: SMT versus B: sham SMT (n=3)3) A: SMT versus B: all other therapies (n=21)4) A: SMT plus any intervention versus B: that same intervention alone (n=5)	Cochrane Back Group 20

Appendix E38. Data Abstraction of Systematic Reviews of Spinal Manipulation

Author, Year	Methods for Synthesizing Results of Primary Studies	Results	Adverse Events
Rubenstein 2012 (continued)		A +B vs B Pain, mean between-group difference (95% CI) - -1 week (1 study): 0.84 (-0.04 to 1.72) -3 to 6 months (1 study): 0.65 (-0.32 to 1.62) Functional status, standardized mean difference (95% CI) - -1 week (2 studies): -0.41 (-0.73 to -0.10) -1 month (3 studies): -0.09 (-0.39 to 0.21) -3 to 6 months (2 studies): -0.22 (-0.61 to 0.16) Recovery, RR (95% CI) - -1 week (2 studies): 0.88 (0.36 to 2.19) -1 month (2 studies): 1.15 (0.60 to 2.19) -3 to 6 months (2 studies): 0.96 (0.71 to 1.31) Return to work, RR (95% CI) - -6 months (1 study): 1.21 (0.99 to 1.47)	
Rubenstein 2012 (continued)		A1 vs A2 No pooled estimates for any outcome	
Rubenstein, 2011	Random effects model; heterogeneity assessed using eyeball and I2 statistic; funnel plots constructed to test for publication bias; pooled effects assessed for clinical relevance according to predefined cut-offs	high quality: SMT has statistically sig short-term effect on pain and function compared to other interventions; varying quality that SMT has a statistically significant short-term effect on pain and function when SMT is added to another intervention. Effect sizes were small - not clinically relevant. Very low quality evidence that SMT is no more effective than inert interventions or sham SMT for short-term pain relief or functional status.	Not reported

Appendix E38. Data Abstraction of Systematic Reviews of Spinal Manipulation

Author, Year	Comparison	Data Sources	Number and Type of Studies	Interventions and Number of Patients	Methods for Rating Methodological Quality of Primary Studies
Rubenstein, 2011 (continued)				A. Any SMT (n=26) B. Inert interventions ((i.e. detuned short-wave diathermy and detuned ultrasound; n=4) C. Other active interventions (exercise; physical therapy; massage; standard care; back school; n=15) D. Sham SMT (n=3)	
Rubenstein, 2011 (continued)					

Appendix E38. Data Abstraction of Systematic Reviews of Spinal Manipulation

Author, Year	Methods for Synthesizing Results of Primary Studies	Results	Adverse Events
Rubenstein, 2011 (continued)		A vs B Pain, mean between-group difference (95% CI) - -1 month (1 study, HRoB): - 6.00 (-15.82 to 3.82) -3 months (1 study, HRoB): 7.00 (-3.58 to 17.58) Functional status, standardized mean difference (95% CI) - No data available Recovery, RR (95% CI) - -1 month (1 study, HRoB): 1.03 (0.49 to 2.19) -3 months (1 study, HRoB): 0.96 (0.56 to 1.65) Return to work, RR (95% CI) - -1 month (1 study, HRoB): 1.29 (1.00 to 1.65) -6 months (1 study, HRoB): 1.17 (0.97 to 1.40)	
Rubenstein, 2011 (continued)		A vs C Pain, mean difference (95% CI) - -1 month (10 studies, LRoB): -2.76 (-5.19 to 0.32) -3 months (6 studies, LRoB): -4.55 (-8.68 to -0.43) - 6 months (7 studies, LRoB): -3.07 (-5.42 to -0.71) - 12 months (4 studies, LRoB): -0.76 (-3.19 to 1.66) Functional status, standardized mean difference (95% CI) - -1 month (10 studies, LRoB): -0.17 (-0.29 to -0.06) -3 months (8 studies, LRoB): -0.18 (-0.37 to 0.01) -6 months (9 studies, LRoB): -0.12 (-0.23 to 0.00) -12 months (6 studies, LRoB):-0.06 (-0.16 to 0.05) Recovery RR (95% CI): -1 month (3 studies, HRoB): 1.20 (1.04 to 1.37) -3 months (2 studies, HRoB): 1.70 (1.20 to 2.40)- 6 months (1 study): 1.05 (0.81 to 1.38) - 12 months (1 study): 0.87 to 1.55) HRQoL, RR (95% CI) - -1 month (3 studies, HRoB): -0.8 (-0.29 to 0.13) - 3 months 3 studies, HRoB): 0.21 (-0.27 to 0.70)	

Appendix E38. Data Abstraction of Systematic Reviews of Spinal Manipulation

Author, Year	**Comparison**	Data Sources	Number and Type of Studies	Interventions and Number of Patients	Methods for Rating Methodological Quality of Primary Studies
Rubenstein, 2011 (continued)					
Rubenstein 2011 (continued)					

Appendix E38. Data Abstraction of Systematic Reviews of Spinal Manipulation

Author, Year	Methods for Synthesizing Results of Primary Studies	Results	Adverse Events
Rubenstein, 2011 (continued)		A vs D Pain, mean between-group difference (95% CI) - -3 months (1 study, HRoB): 2.50(-9.64 to 14.64) -6 months (1 study, HRoB): 7.10 (-5.16 to 19.36) Functional status, standardized mean difference (95% CI) - -1 month (1 study, HRoB): -0.45,(-0.97 to 0.06) -3 months (1 study, HRoB):0.00, (-0.56 to 0.56) -6 months (1 study, HRoB):0.04, (-0.52 to 0.61) Recovery, RR (95% CI) - -1 week (2 studies): 0.96 (0.50 to 1.85) -1 month (1 study): 0.97 (0.85 to 1.10) -3 months (1 study): 1.00 (0.98 to 1.02)	
Rubenstein 2011 (continued)		A +B vs B Pain, mean between-group difference (95% CI) - -1 week (1 study): 0.84 (-0.04 to 1.72) -3 to 6 months (1 study): 0.65 (-0.32 to 1.62) Functional status, standardized mean difference (95% CI) - -1 week (2 studies): -0.41 (-0.73 to -0.10) -1 month (3 studies): -0.09 (-0.39 to 0.21) -3 to 6 months (2 studies): -0.22 (-0.61 to 0.16) Recovery, RR (95% CI) - -1 week (2 studies): 0.88 (0.36 to 2.19) -1 month (2 studies): 1.15 (0.60 to 2.19) -3 to 6 months (2 studies): 0.96 (0.71 to 1.31) Return to work, RR (95% CI) - -6 months (1 study): 1.21 (0.99 to 1.47)	

Please see Appendix C. Included Studies for full study references.

Appendix E39. Data Abstraction of Randomized Controlled Trials of Spinal Manipulation

Author, Year	Country Number of Centers and Setting	Inclusion Criteria	Number Randomized, Analyzed Attrition	Intervention	Study Participants	Duration of Pain (acute, subacute, chronic)
Balthazard, 2012	Switzerland	Inclusion criteria: 1) aged from 20 to 65 year old, male or female, suffering from nonspecific low back pain with or without symptoms in the lower extremity for a period between 12 and 26 weeks; 2) the usual medication can be continued; exclusion criteria: 1) spinal fracture or surgery within the previous 6 months; 2) pregnancy; 3) neoplasia; 4) spinal infection; 5) spinal inflammatory arthritis; 6) low back pain of visceral origin; 7) severe sensitive and/or motor radicular deficit from nerve root origin of less than 6 months; 8) score of 3/5 or more on the Waddell Score [36]; 9) on sick leaves from work for 6 months or more; 10) psychiatric disorders; 11) opioid medication	Randomized: 42 Analyzed: 37 Attrition: 5/42	A. HVLA + 5-10 min active exercises (n=22) B. Detuned ultrasound (sham) + 5-10 min active exercises (n=20)	A vs B Mean age 44 vs 42 years 36% vs 30% female Race not reported Pain VAS 53 vs. 65 ODI: 30 vs. 32	Chronic: 12-26 weeks
Bicalho, 2010	Brazil, sites not stated	Inclusion criteria: age 18 to 55, LBP 3+ months, no treatment or SMT within the last 6 months. Exclusion criteria: pain radiating below the knee, skeletal or neuromuscular disorders identified by imaging or any Accident Compensation Corporation red flags	Randomized: 40 Analyzed:40 Attrition: 0%	A. HVLA (n=20) B. Control (side lying) (n=20)	A vs B Mean age 30 vs 27 ODI: 14.6 vs. 16.6 Race not reported (Brazil)	Chronic >3 months

Appendix E39. Data Abstraction of Randomized Controlled Trials of Spinal Manipulation

Author, Year	Outcome Measures	Duration of Followup	Results	Adverse Events Including Withdrawals	Funding Source	Quality
Balthazard, 2012	Pain intensity (VAS scale 0-10; higher score=more pain) ODI (scale 0-100; higher score=more disability)	Up to 6 months	A vs B Pain, VAS-pain mean group difference: -1.24; 95% CI: -2.37 to − 0.30; P = 0.032, statistically not significant at the 0.025 level. A vs B ODI mean group difference: -7.14; 95% CI: -12.8 to − 1.52; P = 0.013	AEs not reported	Swiss National Science Foundation	Fair
Bicalho, 2010	Pain intensity (VAS scale 0-10; higher score=more pain) ODI (scale 0-100; higher score=more disability)	immediate	A vs B Pain VAS mean group difference (0-100): -11 vs. -2.2, no CI provided, p=0.04) A vs B Finger to floor, EMG flex-ext reported (favored SMT), ODI measured but not reported	AE's not reported	Not reported	Fair

Appendix E39. Data Abstraction of Randomized Controlled Trials of Spinal Manipulation

Author, Year	Country Number of Centers and Setting	Inclusion Criteria	Number Randomized, Analyzed Attrition	Intervention	Study Participants	Duration of Pain (acute, subacute, chronic)
Bronfort, 2004	USA, 1 center	18-65 sciatica >=4 weeks Quebec Classification Category 2,3,4 or 6 Excluded: spinal fracture, spinal stenosis, or other diagnoses, including visceral diseases, compression fractures, and metastases, progressive neurological deficits, cauda equina syndrome, surgical lumbar spine fusion, contraindications to study treatments, a leg pain score of less than 3, current or pending litigation, or ongoing treatment for low back and leg pain from other health care providers. Pregnant or nursing	Randomized = 32 Analyzed = NR Attrition = NR	A = chiropractic (n=11) B = epidural steroid injection (n=11) C = self-care education (n = 10)	A vs B vs C Mean Age: 44 vs 52 vs 52 Female = 45% v 36% v 50% RMD = 43 vs 56 vs 41 Smoker = 1 vs 4 vs 3 QTF Classification 2 = 5 vs 4 vs 4 QTF Classification 3 = 5 vs 6 vs 5 QTF classification 4 = 1 vs 1 vs 1 Low back pain score: 4 vs 6 vs 5 Leg pain score: 6 vs 5 vs 5	A vs B vs C 1-3 mo = 2 vs 2 vs 2 4-6 mo = 1 vs 1 vs 0 7-12 mo = 2 vs 0 vs 1 >12 mo = 7 vs 7 vs 7

Appendix E39. Data Abstraction of Randomized Controlled Trials of Spinal Manipulation

Author, Year	Outcome Measures	Duration of Followup	Results	Adverse Events Including Withdrawals	Funding Source	Quality
Bronfort, 2004	Self-report questionnaires straight leg raise lumbar spinal motion Roland Morris Disability Oswestry Disability National Health Interview Survey	52 weeks	All results were compiled together, no group comparisons 3 week outcomes Leg Pain = 1.8 (Effect Size 1.1) Low back pain = 0.9 (0.4) Roland Morris = 13.7 (0.6) Oswestry 11 (0.9) Bothersome symptoms = 14.6 (0.91) Frequency of symptoms = 12.4 (0.74) Cut back on activities = 3.3 (0.38) Stayed in bed (# days) = 0.2 (0.08) Missed work or school = 0.8 (0.15) 12 week outcomes Leg Pain = 2.9 (Effect Size 1.71) Low back pain = 1.7 (0.8) Roland Morris = 22.7 (1.1) Oswestry 22.9 (1.8) Bothersome symptoms = 25.2 (1.58) Frequency of symptoms = 23.0 (1.37) Cut back on activities = 5.3 (0.61) Stayed in bed (# days) = 1.2 (0.47) Missed work or school = 1.9 (0.35) 52 week outcomes Leg Pain = 2.3 (Effect Size 1.35) Low back pain = 1.9 (0.9) Roland Morris = 19.6 (0.9) Oswestry 15.6 (1.2) Bothersome symptoms = 18.1 (1.13) Frequency of symptoms = 17.5 (1.04) Cut back on activities = 5.3 (0.61) Stayed in bed (# days) = 0.5 (0.20) Missed work or school = 2.3 (0.43)	NR	Foundation for Chiropractic Education and Research.	Poor

Appendix E39. Data Abstraction of Randomized Controlled Trials of Spinal Manipulation

Author, Year	Country Number of Centers and Setting	Inclusion Criteria	Number Randomized, Analyzed Attrition	Intervention	Study Participants	Duration of Pain (acute, subacute, chronic)
Burton,1999	England, one	18-60 years unilateral sciatica from lumbar disc herniation based on CT or MRI no surgical intervention needed Exclusion: Sequestrated herniation multiple level DJD previous lumbar surgery previous chemonucleolysis previous manipulation for present complaint litigation	Randomized = 40 Analyzed = 40 at 2 weeks, 37 at 6 weeks, 30 at 12 months Attrition = 10	A = osteopathic manipulation (15 min treatment sessions over 12 weeks) B = chemonucleolysis (control)	Mean Age 42 53% female a= mean 30 weeks symptoms b = mean 32 weeks	Chronic pain

Appendix E39. Data Abstraction of Randomized Controlled Trials of Spinal Manipulation

Author, Year	Outcome Measures	Duration of Followup	Results	Adverse Events Including Withdrawals	Funding Source	Quality
Burton,1999	leg pain (0-10 scale) Back pain (0-10 scale) Roland Disability scale	12 months	A vs B (* = statistically sig, p value not provided) Baseline leg pain 4 vs 3.7 Back pain 3.8 vs 4.1* RDQ 11.9 vs 12 2 weeks leg pain 3.2 vs 3.3 back pain 3.2 vs 4 RDQ 10.2 vs 13.9* 6 weeks leg pain 2.7 vs 2.7 back pain 2.7 vs 3.6* RDQ 7.8 vs 11 12 months leg pain 2.1 vs 2.3 back pain 2.3 vs 2.9 RDQ 5.9 vs 7.3	NR	NHS Executive	Poor

Appendix E39. Data Abstraction of Randomized Controlled Trials of Spinal Manipulation

Author, Year	Country Number of Centers and Setting	Inclusion Criteria	Number Randomized, Analyzed Attrition	Intervention	Study Participants	Duration of Pain (acute, subacute, chronic)
Cecchi, 2010	Italy, 1 site	Inclusion criteria: Home dwelling, seeking care from rehab department, nonspecific low back pain, reported 'often' to 'always' at least for the past 6 months Exclusion criteria: neurological signs or symptoms, spondylolisthesis 4 second degree, spinal stenosis, lumbar scoliosis 420 degrees, rheumatoid arthritis or spondylitis, previous vertebral fractures, psychiatric disease, cognitive impairment or pain-related litigation	Randomized: 210 Analyzed: 205 Attrition: 2.5% 5/210	A. Back school (n=70) B. PT (n=70) C. SMT (n=70)	A vs B vs C Mean age 58 vs. 61 vs 58 49% vs 43% vs 48% female Race not reported (Italy) Pain, NRS (mean): 2 vs 2 vs 2.2 RMQ (0-24) (mean): 9.5 vs 9.7 vs 8.5 (sick leave due to LBP higher in A vs B and C – p =0.001)	Chronic > 6 months

Appendix E39. Data Abstraction of Randomized Controlled Trials of Spinal Manipulation

Author, Year	Outcome Measures	Duration of Followup	Results	Adverse Events Including Withdrawals	Funding Source	Quality
Cecchi, 2010	Pain intensity (VAS scale 0-10; higher score=more pain) RDQ (scale 0-23; higher score=more disability)	3, 6 and 12 months	A vs B vs C Mean differences not reported – will need to calculate Back Pain NRS 12 month mean change from baseline (0.7 vs 0.4 vs. 1.5) C improved to greater degree than B or A at 12 months in terms of pain (but small, clinically insignificant) A vs B vs C RMQ mean (SD) reduction from baseline to 12 months: 4.2+/- 4.8 vs. 4.0+/-5.1 vs. 5.9+/-4.6 C improved to greater degree than B or A at 12 months in terms of disability (but small, clinically insignificant)	No AEs reported by patients, no drop-outs due to AEs	Fondazione Don Gnocchi Foundation, Scientific Institute	Fair

Appendix E39. Data Abstraction of Randomized Controlled Trials of Spinal Manipulation

Author, Year	Country Number of Centers and Setting	Inclusion Criteria	Number Randomized, Analyzed Attrition	Intervention	Study Participants	Duration of Pain (acute, subacute, chronic)
Cho 2013	Korea 3 hospital-based clinics	Age 18-65 years with nonspecific chronic LBP at least 3 months duration, VAS >5 (scale 0-10) and intact on neurological exam. Exclude: Sciatic pain, pain mainly below the knee, serious spinal disorders, vertebral fracture, spinal infection, inflammatory spondylitis, cauda equina compression, history of spinal surgery or scheduled surgery, other acupuncture treatment, severe psychiatric or psychological disorder, history of corticosteroid, narcotic, muscle relaxant or herbal medicine to treat LBP.	Randomized: 130 Analyzed: 116 Attrition: 11% (14/130)	A. Acupuncture 2x/week for 6 weeks (n=57) B. Sham acupuncture with blunt needles (n=59)	A vs B Mean age 42 vs 42 years 82% vs 86% female Race not reported Pain intensity 6.52 vs 6.37 Pain bothersomeness 6.44 vs 6.32 ODI (Korean version) 28.23 vs 24.17 (p=0.04) SF-36 (Korean version) 107.72 vs 110.41 (unclear which subscales were used) BDI (Korean version)11.33 vs 11.75	Chronic: Mean duration not reported; inclusion criteria required ≥3 months duration at study entry

Appendix E39. Data Abstraction of Randomized Controlled Trials of Spinal Manipulation

Author, Year	Outcome Measures	Duration of Followup	Results	Adverse Events Including Withdrawals	Funding Source	Quality
Cho 2013	Pain intensity (VAS scale 0-10; higher score=more pain) Pain bothersomeness (VAS scale 0-10; higher score=more bothersomeness) ODI (scale 0-100; higher score=more disability) SF-36 (scale 0-100 for each subscale; higher score=less disability) BDI (scale 0-63; higher score=greater depression)	6 months	A vs B <u>8-week outcomes (primary endpoint)</u> Pain intensity: 3.00 (SD 2.41) vs 4.10 (SD 1.85); p=0.007; mean change from baseline 0.53 (SD 0.39) vs 0.35 (SD 0.29); p=0.007 Pain bothersomeness: 3.08 (SD 2.44) vs 4.05 SD 1.84); p=0.02; mean change from baseline 0.53 (SD 0.34) vs 0.35 (SD 0.30); p=0.003 ODI, mean change from baseline: 0.42 (SD 0.39) vs 0.29 (SD 0.44); p=0.10 SF-36, mean change from baseline: 0.20 (SD 0.23) vs 0.16 (SD 0.13); p=0.006 BDI, mean change from baseline: 0.39 (SD 0.56) vs 0.26 (SD 0.83); p=0.34 <u>6-month outcomes</u> Pain intensity: 2.79 (SD 2.44) vs 3.52 (SD 2.53); p=0.11; mean change from baseline 0.56 (SD 0.41) vs 0.44 (SD 0.41); p=0.12 Pain bothersomeness: 2.85 (SD 2.44) vs 3.63 SD 2.37); p=0.08; mean change from baseline 0.56 (SD 0.38) vs 0.41 (SD 0.39); p=0.04 ODI, mean change from baseline: 0.44 (SD 0.38) vs 0.24 (SD 1.10); p=0.20 SF-36, mean change from baseline: 0.20 (SD 0.23) vs 0.14 (SD 0.15); p=0.09 BDI, mean change from baseline: 0.44 (SD 0.58) vs 0.36 (SD 0.66); p=0.49	A vs B Withdrawals: 11% (7/65) vs 11% (7/65); RR 1.00 (95% CI 0.37 to 2.69) Withdrawals due to AEs: Not reported Serious AEs: None in either group Any AE: 15% (10/65) vs 26% (17/65); RR 0.59 (95% CI 0.29 to 1.19) Pain at acupuncture site: 3% (2/65) vs 3% (2/65); RR 1.00 (95% CI 0.15 to 6.89) Bruise at acupuncture site: 2% (1/65) vs 0% (0/65); RR 3.00 (95% CI 0.12 to 72) Worsened LBP: 6% (4/65) vs 12% (8/65); RR 0.50 (95% CI 0.16 to 1.58)	Not reported	Good

Appendix E39. Data Abstraction of Randomized Controlled Trials of Spinal Manipulation

Author, Year	Country Number of Centers and Setting	Inclusion Criteria	Number Randomized, Analyzed Attrition	Intervention	Study Participants	Duration of Pain (acute, subacute, chronic)
de Olivera, 2013	Brazil, 1 outpatient PT clinic	Inclusion criteria: chronic nonspecific low back pain (12+ weeks) aged 18 to 80 years, minimum pain intensity score of 3 on an 11-point numeric pain rating scale (ranging from 0 to 10 points) Exclusion criteria: contraindications to the treatment (e.g., spinal canal stenosis, spinal fracture, acute rheumatic diseases, hemorrhagic diseases, active tuberculosis, recent deep vein thrombosis), pregnancy, nerve root compromise, and previous spinal surgery	Randomized: 148 Analyzed:148 Attrition:0%	A: HVLA – region specific (n=74) B: HVLA non-specific (n=74)	A vs B Mean age 46 vs. 46 80% vs 68% female Race not reported Pain, NPRS 6.1 vs 6.0 Disability, RMDQ: 11.3 vs 9.3	Chronic > 12 weeks
Goertz, 2013	William Beaumont Army Medical Center (WBAMC), Fort Bliss, El Paso, TX	Eligibility criteria: male and female US active-duty military personnel between 18 and 35 years of age with acute LBP, less than 4 weeks duration. Soldiers were excluded if they were relocating or leaving the post within 6 weeks from the day of the screening, had LBP for more than 4 weeks, were pregnant, or had a condition in which CMT was contraindicated	Randomized: 91 Analyzed:73 Attrition: 24% (22/91)	A: HVLA + standard medical care (n=45) B: Standard medical care (n=46)	A vs B Mean age 25 vs. 26 15% vs 14% female 73% vs. 52% White, more missing in SMC Pain, NPRS 5.8 vs. 5.8 Disability, RMDQ: 11 vs. 12.7	Chronic

Appendix E39. Data Abstraction of Randomized Controlled Trials of Spinal Manipulation

Author, Year	Outcome Measures	Duration of Followup	Results	Adverse Events Including Withdrawals	Funding Source	Quality
de Olivera, 2013	Pain intensity (VAS scale 0-10; higher score=more pain) RDQ (scale 0-23; higher score=more disability)	immediate	A vs B Pain, intensity (NRS) mean group difference: 0.50 (-0.10 to 1.10), P=.10 A vs B Pressure pain thresholds measured, no difference between groups, RDQ not reported	AEs not reported	Not reported	Good
Goertz, 2013	Pain intensity (VAS scale 0-10; higher score=more pain) RDQ (scale 0-23; higher score=more disability)	4 weeks	4 week outcomes: A vs B Pain, intensity (NRS) mean group difference: 1.2 (0.2, 2.3) p = 0.02 A vs B Disability (RMQ): 4.0 (1.3, 6.7), p=0.004	No SAEs reported. Two mild AEs (increased sharp pain at site)	Samueli Institute, NIH	Fair

Appendix E39. Data Abstraction of Randomized Controlled Trials of Spinal Manipulation

Author, Year	Country Number of Centers and Setting	Inclusion Criteria	Number Randomized, Analyzed Attrition	Intervention	Study Participants	Duration of Pain (acute, subacute, chronic)
Haas, 2014	University of Western States, Portland, OR, 1 site	Inclusion criteria: 18+ years old, current episode of cLBP of mechanical origin of 3+ months duration, some LBP on 30 days in the previous 6 weeks and a minimum LBP index of 25 on a 100-point scale. Exclusion criteria: received manual therapy within the previous 90 days or for contraindications to study interventions and complicating conditions such as active cancer, spine pathology, inflammatory arthropathies, autoimmune disorders, anticoagulant conditions, neurodegenerative diseases, pain radiating below the knee, organic referred pain, pregnancy, and disability compensation	Randomized: 400 Analyzed: 391 Attrition: =2.3% (9/400)	A: Massage (n=100) B. Massage + 6 SMT (n=100) C. Massage + 12 SMT (n=100) D. Massage + 18 SMT (n=100)	A vs B vs C vs D Mean age 41 vs. 41 vs 42 vs 41 49% vs 49% vs 49% vs 52% female Nonwhite: 14% vs. 18% vs 11% vs 16% Pain, VAS 52.2 vs 51.0 vs 51.6 vs 51.5	Chronic >3 months

Appendix E39. Data Abstraction of Randomized Controlled Trials of Spinal Manipulation

Author, Year	Outcome Measures	Duration of Followup	Results	Adverse Events Including Withdrawals	Funding Source	Quality
Haas, 2014	Primary outcomes: pain score is the average of three 11-point numeric rating scales converted to a 100-point scale: back pain today, worst back pain in the last 4 weeks, and average back pain in the last 4 weeks. The disability score is also the average of three scales: interference with daily activities, social and recreational activities, and the ability to work (outside or around the house). Secondary outcomes included pain unpleasantness, Physical and Mental Component Summary Scales of the short-form 12, Health State Visual Analog Scale from EuroQol, perceived pain and disability improvement, and the number of the following in the previous 4 weeks: days with pain and disability and medication use	up to 52 weeks	A vs D Pain intensity, percentage responders (>50%) at 52 weeks 10.6 (-3.2, 24.4), NS NS differences in A vs B, A vs C Only sig diff in 12 week A vs C 21.1 (7.7, 34.6)* p <0.025 Disability score calculated, but unclear what measure	No SAEs; 4 participants had increased back pain. One withdrew due to exacerbation from lifting a child.	NCCAM	Good

Appendix E39. Data Abstraction of Randomized Controlled Trials of Spinal Manipulation

Author, Year	Country Number of Centers and Setting	Inclusion Criteria	Number Randomized, Analyzed Attrition	Intervention	Study Participants	Duration of Pain (acute, subacute, chronic)
Matthews, 1987	England, one	18-60 years 3 months of symptoms	Randomized = 291 Analyzed = 260 Attrition = Trial A vs B 7.0% (4/57); Trial C vs D 11% (207/233) 52 withdrew or stopped treatment, but analyzed many of these as above	A. SMT (n=32) B. Heat (n=25) (LBP patient only) C. SMT (n=132) D. Heat (n=101) (sciatica)	A vs B vs C vs D Mean age 38 vs 40 vs 35 vs 38 15/32 vs 10/25 vs 50/132 vs 35/101 female Race, pain , function not reported	Acute to subacute LBP (<3 months)
Paatelma, 2008	Finland, 4 clinics	Inclusion criteria: 18–65-year-old employed people with current non-specific LBP with or without radiating pain to one or both lower legs. The back pain episode could be acute to chronic, the first or recurrent. Exclusion criteria were: pregnancy, low back surgery less than 2 months previously, and “red flags” that indicate serious spinal pathology	Randomized: 134 Analyzed:106 Attrition: =21% (28/134)14% in the McKenzie method group, to 22% in the OMT group, to 30% in the advice-only group	A. SMT (n = 45) B. McKenzie (n = 52), C. “advice only to be active” (n = 37)	A vs B vs C Mean age 44 vs. 44 vs 44 42% vs 29% vs 35% female Race not reported (Finland) Pain, VAS (median): 20 vs 16 vs 16 RMQ (0-24) (median): 9 vs 9 vs 8	duration not specified

Appendix E39. Data Abstraction of Randomized Controlled Trials of Spinal Manipulation

Author, Year	Outcome Measures	Duration of Followup	Results	Adverse Events Including Withdrawals	Funding Source	Quality
Matthews, 1987	Pain numeric rating scale (0-10) and 6 point VAS; those with 5-6 on VAS were "recovered" and 1-4 "not recovered"	2 weeks	2 week outcomes: Only “recovery rate” was reported in percentages for the group A vs B 62% vs 70% p>0.05 C vs D 80% vs 67% 2 weeks p<0.01	AEs not reported	Dept of Health and Social Security and Special Trustees, St. Thomas Hospital	
Paatelma, 2008	Pain intensity (VAS scale 0-10; higher score=more pain) Pain bothersomeness (VAS scale 0-10; higher score=more bothersomeness) RDQ (scale 0-23; higher score=more disability)	1 year	A vs C (12 months) Pain, intensity (VAS) mean group difference: –4 (–17 to 9) p= 0.714 B vs C Pain, intensity (VAS) mean group difference: –10 (–23 to 2) p = 0.144 A vs C (12 months) Disability (RMQ): –3 (–6 to 0) p= 0.068 B vs C Disability (RMQ): –3 (–6 to 0) 0.028	AEs not reported	Not reported	Fair

Appendix E39. Data Abstraction of Randomized Controlled Trials of Spinal Manipulation

Author, Year	Country Number of Centers and Setting	Inclusion Criteria	Number Randomized, Analyzed Attrition	Intervention	Study Participants	Duration of Pain (acute, subacute, chronic)
Petersen, 2011	Denmark, 1 primary care clinic	Eligible patients were between 18 and 60 years of age, suffering from LBP with or without leg pain for a period of more than 6 weeks, able to speak and understand the Danish language, and with a presentation of clinical signs of disc-related symptoms Exclusion criteria: were free of symptoms at the day of inclusion, demonstrated positive nonorganic signs, 19 or if serious pathology was suspected based on physical examination and/or magnetic resonance imaging, application for disability pension, pending litigation, pregnancy, comorbidity, recent back surgery, language problems, or problems with communication including abuse of drugs or alcohol	Randomized: 350 Analyzed: 324 Attrition: 10% (26/350) 91 patients "withdrew" from treatment, but a total of 324/350 were followed to the end of the study	A. McKensie exercise (n=175) B. SMT (n=175)	A vs B Mean age 38 vs. 37 59% vs 53% female Race not reported (Denmark) Pain (3 0-10 scales), 30/60 vs 29/30 Disability, RMDQ: 13 vs. 13	Chronic >6 weeks

Appendix E39. Data Abstraction of Randomized Controlled Trials of Spinal Manipulation

Author, Year	Outcome Measures	Duration of Followup	Results	Adverse Events Including Withdrawals	Funding Source	Quality
Petersen, 2011	Primary outcome: RDQ (scale 0-23; higher score=more disability) Secondary outcomes: Pain intensity (VAS scale 0-10; higher score=more pain), global perceived effect, 29 quality of life, 30 days with reduced activity, 31 return-to-work, satisfaction with treatment, and use of health care after the completion of treatment	2 months	A vs. B. Pain, intensity (NRS) mean group difference: 2.8 (− 0.2 to 5.8) P = 0.063 (12 months) A vs B Disability (RMQ): 1.5 (0.2 to 2.9) P = 0.030 (12 months, favoring A)	AEs not reported; 28 from Mckensie group "withdrew" from treatment due to lack of effect, but were followed to end of study; 48 from SMT group withdrew due to lack of effect.	Grants, Foundation funds, but not specified	Good

Appendix E39. Data Abstraction of Randomized Controlled Trials of Spinal Manipulation

Author, Year	Country Number of Centers and Setting	Inclusion Criteria	Number Randomized, Analyzed Attrition	Intervention	Study Participants	Duration of Pain (acute, subacute, chronic)
Santilli, 2006	Italy, two	18-65 acute pain <10 days Moderate to severe pain (>5 on VAS) Pain radiating to one leg MRI evidence of disc protrusion	Randomized = 102 (53 vs 49) Analyzed = 102 Attrition = 6	A = active manipulation 5 days/week B = control (simulated manipulation)	Mean age <40 Female 30% vs 45% Pain 6.4 vs 6.4 Radiating Pain 5.3 vs 5.1	Acute
Senna, 2011	Egypt, 1 hospital	Inclusion criteria: 20 to 60years old with chronic nonspecific LBP (that lasted for at least 6 months) Exclusion criteria: “red flags” for a serious spinal condition, structural deformity, spondylolisthesis, spinal stenosis, ankylosing spondylitis, osteoporosis, prior surgery to the lumbar spine or buttock, obvious psychiatric disorders, referred pain to the back, widespread pain (e.g. , fibromyalgia), obese patients, current pregnancy, patients older than 60 years or younger than 20 years, and patients who had previous experience with SMT	Randomized: 93 Analyzed:60 Attrition: =35% (33/93)	A. sham SMT (12 sessions over 1 month) (n=40) B. SMT (12 sessions over 1 month) (n=27) C. SMT (12 sessions over 1 month + every 2 weeks x 9 months) (n=27)	A vs B vs C Mean age 42 vs. 40 vs 42 24% vs 27% vs 24% female Race not reported (Egypt) Pain, VAS 41 vs 42 vs 43 ODI: 38 vs 39 vs 40	Chronic > 6 months

Appendix E39. Data Abstraction of Randomized Controlled Trials of Spinal Manipulation

Author, Year	Outcome Measures	Duration of Followup	Results	Adverse Events Including Withdrawals	Funding Source	Quality
Santilli, 2006	Pain days VAS pain score NSAID use SF-36	180 days	A vs B 180 days No. of patients with reduction of local pain 98% vs 94% (NS) No. of patients with reduction of radiating pain 100% vs 83% (p<0.01) No. of Patients pain free (local pain) 28% vs 6% (p<0.005) No. of Patients who are pain free (radiating pain) 55% vs 20% (p<0.001) NS difference between SF-36 results	None reported	No profit Institute of Rome	Good
Senna, 2011	Pain intensity (VAS scale 0-10; higher score=more pain) SF-36 (scale 0-100 for each subscale; higher score=less disability) Global perception of improvement	1, 4, 7, 10 months	A vs B vs C Pain, intensity (NRS) mean group difference: A vs B Unadjusted mean difference in VAS at 1 month 4; at 10 months 0 A vs C Unadjusted mean difference at 1 month 6, at 10 months 17 Results not reported as group mean differences – will need to calculate these; overall B and C improved to similar degree compared to A at 1 month, group C maintained the improvement through 10 months whereas B returned to baseline for both pain and function	Most common: local tenderness and tiredness (frequency not reported), no SAEs	No funds	Fair

Appendix E39. Data Abstraction of Randomized Controlled Trials of Spinal Manipulation

Author, Year	Country Number of Centers and Setting	Inclusion Criteria	Number Randomized, Analyzed Attrition	Intervention	Study Participants	Duration of Pain (acute, subacute, chronic)
von Heymann, 2013	Germany, 5 orthopedic or general practices in 4 different cities	Inclusion criteria: 18 to 55 years of age, acute (< 48 hr) LBP. Exclusion criteria: known intolerance to NSAID or paracetamol, occurrence of LBP or spinal manipulation for any cause within the last 3 months, known or suspected abuse of alcohol or drugs, metabolic or malignant or any serious organic or neurological disease, atopic diathesis, any structural disturbances of the spine	Randomized: 101 Analyzed:93* Attrition: ?8% (8/101) Very unclear description and text does not match the consort diagram	A. SMT and placebo-diclofenac (n=37) B. Sham SMT and diclofenac (n=38) C. Sham SMT and placebo diclofenac. (n=25)	A vs B vs C Mean age 34 vs. 38 vs 39 36% vs 38% vs 46% female Race not reported (Germany) Pain, VAS 41 vs 42 vs 43 ODI: 38 vs 39 vs 40	Acute <48 hours

Appendix E39. Data Abstraction of Randomized Controlled Trials of Spinal Manipulation

Author, Year	Outcome Measures	Duration of Followup	Results	Adverse Events Including Withdrawals	Funding Source	Quality
von Heymann, 2013	Pain intensity (VAS scale 0-10; higher score=more pain) RDQ (scale 0-23; higher score=more disability) SF-12	12 weeks	A vs B vs C (only reported to 9 days) Pain VAS – unable to calculate group mean differences based on the way presented (graphs) And only A vs B was presented, not A vs B vs CA vs. B. vs C. A vs B: Unadjusted mean difference in RMQ at 12 weeks: 3.0 (? P value) RMQ - unable to calculate group mean differences based on the way presented (graphs)	No AEs reported by patients; Early termination due to treatment failure occurred in 10 of 22 subjects in the placebo group. In the spinal manipulation group, 1 of the 35 subjects opted out early because of treatment failure. In the diclofenac group 3 of the 35 subjects opted out early because of treatment failure	Deutsche Gesellschaft für Manuelle Medizin (DGMM) - Aerzteseminar für Manuelle Wirbelsaeulenund Extremitaetentherapie (MWE)	Fair

Please see Appendix C. Included Studies for full study references.

Appendix E40. Trials of Ultrasound Included in the APS/ACP Review

Author, Year, Title	Purpose of Study	Study Design	Inclusion Criteria	Exclusion Criteria	Number of Treatment and Control Subjects (number approached, number eligible, number enrolled)
Ansari, 2006 A randomized, single blind placebo controlled clinical trial on the effect of continuous ultrasound on low back pain	To assess benefits of ultrasound versus sham ultrasound in patients with chronic low back pain	Parallel-group RCT	Age 18 to 65, nonradiating nonspecific low back pain, present more than 3 months	Abnormal neurologic status, concomitant severe disease, psychiatric illness, current psychotherapy, pathological lumbosacral X-rays, rheumatic inflammatory disease, planned hospitalization, substance abuse, contraindication to ultrasound therapy	58 approached 15 eligible and enrolled (7 ultrasound, 8 sham ultrasound)
Nwuga, 1983 Ultrasound in treatment of back pain resulting from prolapsed intervertebral disc	To assess benefits of ultrasound versus sham ultrasound for low back pain with prolapsed intervertebral disc	nonrandomized controlled clinical trial	Prolapsed lumbar intervertebral disc (L4 to S2), documented with studies including myelography and electrodiagnostic studies, unable to work due to severity of symptoms, unilateral referred pain or numbness, no prior treatment for this condition, onset within 2 weeks, ability to perform straight leg raising less than 40 degrees	Not specified	Number approached and eligible not reported 73 enrolled (27 ultrasound, 25 sham ultrasound, 29 no treatment)
Roman, 1960 A clinical evaluation of ultrasound by use of a placebo technic	To assess benefits of ultrasound vs. sham ultrasound for chronic low back pain	Parallel-group RCT	Low back pain, other inclusion criteria not specified	Not specified	Number approached and eligible not reported 36 enrolled (18 ultrasound, 18 sham ultrasound)

Appendix E40. Trials of Ultrasound Included in the APS/ACP Review

Author, Year, Title	Subject Age, Gender, Diagnosis	Country and Setting	Sponsor	Measures
Ansari, 2006 A randomized, single blind placebo controlled clinical trial on the effect of continuous ultrasound on low back pain	Mean age: 35 vs. 26 years Female gender: 0% vs. 60% nonwhite race: Not reported Duration of low back pain: 14 vs. 15 months Severity of baseline pain: Not reported	Iran Rehabilitation physiotherapy clinic Single center	Not reported	Functional rating Index (sum of scores for 10 items, each rated 0 to 4, standardized to a 0 to 100 scale) Range of motion, electrophysiologic evaluation
Nwuga, 1983 Ultrasound in treatment of back pain resulting from prolapsed intervertebral disc	Baseline data not reported by intervention group Mean age: 44 years Female gender: 0% nonwhite race: Not reported Duration of low back pain: <2 weeks Severity of baseline pain: Not reported	Nigeria Physical therapy department Single center	Not reported (gel supplied by Parka Laboratories, inc)	Proportion pain free or with some improvement Straight leg raise testing Lumbar range of motion
Roman, 1960 A clinical evaluation of ultrasound by use of a placebo technic	Baseline data not reported	USA Type of clinic and number of centers not reported	Not reported	Overall assessment (negative, poor, fair, good, normal)

Appendix E40. Trials of Ultrasound Included in the APS/ACP Review

Author, Year, Title	Type of Intervention	Results	Duration of Followup
Ansari, 2006 A randomized, single blind placebo controlled clinical trial on the effect of continuous ultrasound on low back pain	A: Ultrasound 1.5 w/cm^2 at frequency of 1 MHz for 10 sessions, three days per week B: Sham ultrasound	Ultrasound vs. sham ultrasound Functional Rating Index (mean change from baseline): -22 vs. -7 ($p<0.05$)	Immediately after 3 weeks of treatment sessions
Nwuga, 1983 Ultrasound in treatment of back pain resulting from prolapsed intervertebral disc	A: Ultrasound 1 to 2 w/cm^2 for 10 minutes + bed rest, mean 11 sessions B: Sham ultrasound + bed rest, mean 12 sessions C: No ultrasound (bed rest + analgesics)	Ultrasound vs. sham ultrasound vs. no ultrasound (bed rest in all groups) Proportion pain free: 41% (11/27) vs. 12% (3/25) vs. 7% (2/29) ($p<0.001$ for ultrasound versus sham or no ultrasound)	Immediately after 4 weeks of treatment sessions
Roman, 1960 A clinical evaluation of ultrasound by use of a placebo technic	A: Ultrasound 1 to 1.5 w/cm^2 for 8 to 10 minutes up to 10 treatments + moist heat + mobilization exercises B: Sham ultrasound + moist heat + mobilization exercises	Ultrasound vs. sham ultrasound Proportion "normal": 22% (4/18) vs. 11% (2/18) Proportion "normal" or "good": 67% (12/18) vs. 72% (13/18)	Unclear

Appendix E40. Trials of Ultrasound Included in the APS/ACP Review

Author, Year, Title	Loss to Followup	Compliance to Treatment	Adverse Events and Withdrawals Due To Adverse Events	Quality Rating	Comments
Ansari, 2006 A randomized, single blind placebo controlled clinical trial on the effect of continuous ultrasound on low back pain	33% (5/15)	Not reported	Not reported		
Nwuga, 1983 Ultrasound in treatment of back pain resulting from prolapsed intervertebral disc	Treatment terminated early (due to lack of pain) for 4 in treatment and 1 in placebo group.	Not reported	Not reported		
Roman, 1960 A clinical evaluation of ultrasound by use of a placebo technic	None reported	Not reported	Not reported		

Please see Appendix C. Included Studies for full study references.

Appendix E41. Data Abstraction of Systematic Reviews of Ultrasound

Author, Year	Comparison	Data Sources	Number and Type of Studies	Interventions and Number of Patients	Methods for Rating Methodological Quality of Primary Studies
Ebadi, 2014	Ultrasound vs. sham ultrasound (4 RCTs) Ultrasound + exercise vs. exercise (2 RCTs) Ultrasound vs. other treatments (3 RCTs)	Cochrane CENTRAL, MEDLINE, EMBASE PEDro, PsychLIT (through October 2013); reference lists; contacted experts No language restriction	7 RCTs (n=15 to 120) Duration of followup: At end of treatment in all trials except for two trials that evaluated patients 4 weeks and 6 months after end of treatment All trials enrolled patients with chronic low back pain	A: Ultrasound (n=65) B: Sham ultrasound (n=66) C: Ultrasound (n=39) D: No ultrasound (n=40) E: Ultrasound (n=95) F: Other interventions (electrical stimulation, phonophoresis, manipulation (n=96) Exercise therapy in all groups in all trials except for one (n=10)	All studies used 1 MHz continuous ultrasound at intensities from 1 to 2.5 W/cm2, applied for 5-10 minutes or based on Gray's formula; 6 to 18 sessions

Appendix E41. Data Abstraction of Systematic Reviews of Ultrasound

Author, Year	Methods for Rating Methodological Quality of Primary Studies	Methods for Synthesizing Results of Primary Studies	Results	Adverse Events	Quality
Ebadi, 2014	Cochrane Back Review Group 2009 criteria Two of seven RCTs assessed as low risk of bias based on meeting at least 6 of 12 criteria; patients blinded in 4 trials, care providers blinded in 0 trials, 2 trials reported intention-to-treat analysis	Qualitative: GRADE approach Quantitaive: Meta-analysis using random effects model	A vs B Pain (mean difference, 3 trials): -7.12, (95% CI -18.0 to 3.75, I^2=77%, SOE: low) Back-specific function (SMD, 3 trials): -0.45 (95% CI -0.84 to -0.05, I^2=0%, SOE: moderate) C vs. D Pain (mean difference, 2 trials): -21.6 (95% CI -4.66 to 0.34, I^2=0%, SOE: low) Back-specific function (mean difference, 2 trials): -0.41 (-3.14 to 2.32, I^2=0%, SOE: low) E vs. F US vs. electrical stimulation (1 trial, SOE: very low) Pain Disability Index: 6.21 vs. 5.15 (p>0.05) ODI: 8.68 vs. 6.80 (p>0.05) Beck Depression Inventory: 6.52 vs. 7.35 (p>0.05) SF-36: differences ranged from 0 to -11 on SF-36 subscales US vs. phonophoresis (1 trial, SOE: very low) Pain Disability Index: 6.60 vs. 4.90 (p>0.05) ODI: 4.95 vs. 3.65 (p>0.05) Pain (0-10 VAS): 1.35 vs. 1.25 (p>0.05) SF-36: differences ranged from -13.6 to +4.3 on subscales US vs. spinal manipulation (1 trial, SOE: low) Pain (mean difference): -16.4 (95% CI -26.8 to -6.1) at end of treatment, -1.4 (95% CI -2.7 to -0.1) 6 m after end of treatment ODI (mean difference): -7.8 (95% CI -13.2 to -2.4) at end of treatment, -7.4 (95% CI -13.8 to -0.1) 6 m after end of treatment	Not reported (not reported in trials)	Good

Please see Appendix C. Included Studies for full study references.

Appendix E42. Data Abstraction of Randomized Controlled Trials of Ultrasound

Author, Year	Country Number of Centers and Setting	Inclusion Criteria	Number Randomized, Analyzed Attrition	Intervention
Studies included in the APS review				
Ansari, 2006	Iran Rehabilitation physiotherapy clinic Single center	Age 18 to 65, non-radiating non-specific low back pain, present more than 3 months	Randomized: 15 7 vs. 8) Analyzed: 10 Attrition: 33% (5/15)	A: Ultrasound 1.5 w/cm^2 at frequency of 1 MHz for 10 sessions, three days per week B: Sham ultrasound
Nwuga, 1983	Nigeria Single center	Prolapsed lumbar intervertebral disc (L4 to S2), documented with studies including myelography and electrodiagnostic studies, unable to work due to severity of symptoms, unilateral referred pain or numbness, no prior treatment for this condition, onset within 2 weeks, ability to perform straight leg raising less than 40 degrees	Randomized: 72 (27 vs. 25 vs. 29) Analyzed: 67 Attrition: Treatment terminated early due to lack of pain for 4 in treatment and 1 in placebo group.	A: Ultrasound 1 to 2 w/cm^2 for 10 minutes + bed rest, mean 11 sessions B: Sham ultrasound + bed rest, mean 12 sessions C: No ultrasound (bed rest + analgesics)
Roman, 1960	USA Number of centers not reported	Low back pain, other inclusion criteria not specified Exclude: Not specified	Randomized: 36 (18 vs.18) Analyzed: 36 Attrition: Not reported	A: Ultrasound 1 to 1.5 w/cm^2 for 8 to 10 minutes up to 10 treatments + moist heat + mobilization exercises B: Sham ultrasound + moist heat + mobilization exercises
Studies published since the APS review				
Ebadi, 2012	Iran Single center	18 to 60 years of age with non-specific chronic low back pain Exclude: nerve root systems, systemic disease and specific conditions, medications for psychological problems, pregnant	Randomized: 50 Analyzed: 50 Attrition: 18% (12% vs. 24%) at 8 weeks	A: Ultrasound 1.5 W/cm^2 at 1 MHz; duration based on Grey's formula, 10 sessions over 4 weeks (n=25) B: Sham ultrasound, same technique as A but no US (n=222)

Appendix E42. Data Abstraction of Randomized Controlled Trials of Ultrasound

Author, Year	Study Participants	Duration of Pain (acute, subacute, chronic)	Duration of Followup
Studies included in the APS review			
Ansari, 2006	Mean age: 35 vs. 26 years Female gender: 0% vs. 60% Non-white race: Not reported Duration of low back pain: 14 vs. 15 months Severity of baseline pain: Not reported	Chronic	Immediately after 3 weeks of treatment sessions
Nwuga, 1983	Baseline data not reported by intervention group Mean age: 44 years Female gender: 0% Non-white race: Not reported Duration of low back pain: <2 weeks Severity of baseline pain: Not reported	Not reported	Immediately after 4 weeks of treatment sessions
Roman, 1960	Baseline data not reported.	Chronic	Unclear
Studies published since the APS review			
Ebadi, 2012	A vs B Mean age: 31 vs. 37 years 25% vs 50% female Race: Not reported Pain intensity (mean, 0-100 VAS): 47 vs. 49 Functional Rating Index (mean, 0-100): 41 vs. 44	Chronic: All chronic, mean duration 5.8 vs. 8.1 years	8 weeks (4 weeks after completion of therapy)

Appendix E42. Data Abstraction of Randomized Controlled Trials of Ultrasound

Author, Year	Results (list results for acute, subacute, and chronic separately)	Adverse Events Including Withdrawals	Funding Source	Quality (Cochrane Back Group)	Comments
Studies included in the APS review					
Ansari, 2006	Ultrasound vs. sham ultrasound Functional Rating Index (mean change from baseline): -22 vs. -7 (p<0.05)	Not reported	Not reported	Poor	
Nwuga, 1983	Ultrasound vs. sham ultrasound vs. no ultrasound (bed rest in all groups) Proportion pain free: 41% (11/27) vs. 12% (3/25) vs. 7% (2/29) (p<0.001 for ultrasound versus sham or no ultrasound)	Not reported	Not reported (gel supplied by Parka Laboratories, inc)	Poor	
Roman, 1960	Ultrasound vs. sham ultrasound Proportion "normal": 22% (4/18) vs. 11% (2/18) Proportion "normal" or "good": 67% (12/18) vs. 72% (13/18)	Not reported	Not reported	Poor	
Studies published since the APS review					
Ebadi, 2012	A vs B Pain (mean, 0-100 VAS): 27 vs. 31 at 4 w, 28 vs. 26 at 8 w (p=0.48 for overall effect) Functional Rating Index (mean, 0-100 VAS): 23 vs. 31 at 4 w, 23 vs. 30 at 8 w (p=0.04 for overall effect)	Not reported	Tehran University of Medical Sciences	Fair	

Appendix E42. Data Abstraction of Randomized Controlled Trials of Ultrasound

Author, Year	Country Number of Centers and Setting	Inclusion Criteria	Number Randomized, Analyzed Attrition	Intervention
Licciardone, 2013	United States Single center	21 to 69 years of age, nonpregnant, low back pain >3 months. Exclude: Cancer, spinal osteomyelitis, spinal fracture, herniated disc, ankylosing spondylitis, cauda equina syndrome, low back surgery in last year, workers' compensation benefits in the last 3 months, ongoing litigation involving back problems, angina or congestive heart failure symptoms with minimal activity, history of stroke or transient ischemic attack in past year, implanted biomedical devices, bleeding or infection in the lower back, corticosteroids in the last month, use of manual treatment of ultrasound in the last 3 months or more than 3 times in the past year, no signs of radiculopathy	Randomized: 455 Analyzed: 455 Attrition: 7.4% (9.4% vs. 5.9%) at 12 weeks	A: Ultrasound 1.2 W/cm^2 at 1 MHz; six 10 minute treatments over 8 weeks (n=233) B: Sham ultrasound, at 0.1 W/cm^2, treatment otherwise identical to A (n=222) Factorial design, patients also randomized to osteopathic manual treatment vs. sham treatment; no interaction between treatments
Unlu, 2008	Turkey Single center	20 to 60 years of age, acute leg pain and leg pain of <3 months' duration due to lumbar disc herniation, with MRI verification and concordant symptoms, imaging findings, and physical examination Exclude: Abnormal laboratory findings, systemic and psychiatric illness, pregnant, previous spinal surgery, spinal stenosis, spondylolisthesis	Randomized: 60 Analyzed: 60 Attrition: Not reported	A: Ultrasound 1.5 W/cm^2 at 1 MHz; 15 sessions over 3 weeks (n=20) B: Lumbar traction: Motorized traction system (Tru-trac 401), 15 minutes per session (hold for 30 seconds and rest for 10 seconds), traction forced increased as tolerated from minimum traction force 35% to maximum 50% of body weight; 90 degree hip and knee flexion C: Low-level laser: Gal-Al-As diode laser at 50 mV and wavelength 830 nm, diameter 1 mm, 4 minute application over both sides of disc spaces where herniation detected, dose 1 J at each point

Appendix E42. Data Abstraction of Randomized Controlled Trials of Ultrasound

Author, Year	Study Participants	Duration of Pain (acute, subacute, chronic)	Duration of Followup
Licciardone, 2013	A vs B Median age: 38 vs 43 years 58% vs 68% female Race: Not reported Pain intensity (median, 0-100 VAS): 44 vs. 44 RDQ (median, 0-24): 5 vs. 5 SF-36 general health (median, 0-100): 72 vs. 67	Chronic: All >3 months, 51% vs. 49% >1 year	12 weeks (4 weeks after completion of therapy)
Unlu, 2008	A vs B vs C Mean age: 48 vs. 42 vs. 43 years 65% vs. 80% vs. 65% female Race: Not reported Pain intensity, low back (mean, 0-100 VAS): 52 vs. 58 vs. 54 Pain intensity, leg (mean, 0-100 VAS): 56 vs. 60 vs. 53 RDQ (mean, 0-24): 13 vs. 14 vs. 12 Modified ODI (mean, 0-50): 20 vs. 15 vs. 18	Acute: All <3 months	3 months after completion of therapy

Appendix E42. Data Abstraction of Randomized Controlled Trials of Ultrasound

Author, Year	Results (list results for acute, subacute, and chronic separately)	Adverse Events Including Withdrawals	Funding Source	Quality (Cochrane Back	Comments
Licciardone, 2013	A vs B ≥30% improvement in pain: RR 1.02 (95% CI 0.86 to 1.20) at w 12 ≥50% improvement in pain: RR 1.09 (95% CI 0.88 to 1.35) at w 12 RDQ (median, 0-24): 4 vs. 4 at w 4 (p=0.99), 3 vs. 4 at week 8 (p=0.76), 3 vs. 3 at w 12 (p=0.93) SF-36 general health (median, 0-100): 72 vs. 72 at w 4 (p=0.73), 72 vs. 72 at w 8 (p=0.53), 72 vs. 74 at w 12 (p=0.66) Lost 1 or more days work in past 4 weeks because of low back pain: 16% vs. 7% (p=0.04) at w 4, 17% vs. 8% at w 8 (p=0.54), 13% vs. 6% at w 12 (p=0.11) Very satisfied with back care: 41% vs. 45% at w 4 (p=0.44), 49% vs. 51% at w 8 (p=0.77), 55% vs. 55% at w 12 (p=0.99)	A vs B Withdrawal due to adverse event: Not reported Any adverse event: 6.0% (14/233) vs. 5.9% (13/222), RR 1.03 (95% CI 0.49 to 2.13) Serious adverse event: 1.3% (3/233) vs. 2.7% (6/222), RR 0.48 (95% CI 0.12 to 1.88)	National Institutes of Health-National Center for Complementary and Alternative Medicine and the Osteopathic Heritage Foundation	Good	
Unlu, 2008	A vs B vs C Pain intensity, low back (0-100 VAS): 30 vs. 30 vs. 34 at end of treatment, 27 vs. 26 vs. 31 1 m after end of treatment, 27 vs. 31 vs. 30 3 m after end of treatment Pain intensity, leg (0-100 VAS): 29 vs. 28 vs. 33 at end of treatment, 27 vs. 22 vs. 26 1 m after end of treatment, 25 vs. 30 vs. 24 3 m after end of treatment RDQ (0-24): 9.3 vs. 9.8 vs. 9.9 at end of treatment, 8.2 vs. 8.5 vs. 7.3 1 m after end of treatment, 8.6 vs. 8.9 vs. 6.7 3 m after end of treatment Modified ODI (0-50): 14 vs. 15 vs. 15 at end of treatment, 14 vs. 14 vs. 14 1 m after end of treatment, 14 vs. 15 vs. 14 3 m after end of treatment	Not reported	Not reported	Poor	

Please see Appendix C. Included Studies for full study references.

Appendix E43. Data Abstraction of Systematic Reviews of TENS

Author, Year	Comparison	Data Sources	Number and Type of Studies	Interventions and Number of Patients	Methods for Rating Methodological Quality of Primary Studies
van Middelkoop 2011	TENS vs. sham TENS vs. active treatments	MEDLINE, EMBASE, CINAHL, CCRCT, PEDro through December 2008; reference lists of relevant Cochrane reviews	6 RCTs; n=699 Duration of followup 2-16 weeks All chronic pain	A. TENS B. Other active intervention C. Sham TENS	Cochrane Back Group criteria - 2011

Appendix E43. Data Abstraction of Systematic Reviews of TENS

Author, Year	Methods for Synthesizing Results of Primary Studies	Results	Adverse Events	Quality	Comments
van Middelkoop 2011	Continuous outcomes: scales converted to 100 point scales, weighted mean difference calculated Dichotomous outcomes: RR and CI calculated; heterogeneity assessed using I^2 Funnel plot constructed to assess risk of publication bias	A vs. C Pain score: 4 trials; WMD -4.47 (95% CI -12.84 to 3.89) Disability: 2 trials; WMD -1.36 (95% CI -4.38 to 1.66) A vs. B No meta-analysis; narrative report of 2 trials of exercise or exercise + PENS found no significant difference between TENS and other treatments	Not reported	Good	

Please see Appendix C. Included Studies for full study references.

Appendix E44. Data Abstraction of Randomized Controlled Trials of TENS

Author, Year	Country Number of Centers and Setting	Inclusion Criteria	Number Randomized, Analyzed Attrition	Intervention	Study Participants
Buchmuller 2012	Multi-center France	Age >18 years with chronic low back pain ≥40 VAS with or without radicular pain Excluded: pain duration <3 months, previous TENS treatment, prior surgery for radiculopathy or planned surgery within 6 months, planned use of other treatment for LBP	Randomized: 236 Analyzed: unclear (varied by outcome) Attrition: unclear	A. Active TENS 4 1-hour sessions per day (n=117) B. Sham TENS 4 1-hour sessions per day (n=119)	A vs. B Mean age 53 vs. 53 years 62% vs. 64% female Race not reported LBP alone 39% vs. 43%; LBP + radicular pain: 61% vs. 57% VAS 63 vs. 66 Roland-Morris disability score 15 vs. 15
Facci 2011	Single-center Brazil	Age >18 years with nonspecific, chronic low back pain Excluded: low back pain duration <3 months, receiving other nonpharmacologic treatment, prior back surgery, contraindication to electrotherapy	Randomized: 150 Analyzed: 150 Attrition: 0%	A. TENS 10 30-minutes sessions over 2 weeks (n=50) B. Interferential therapy 10 30-minutes sessions over 2 weeks (n=50) C. No treatment (n=50)	A vs. B vs. C Mean age 50 vs. 45 vs. 47 years 70% vs. 74% vs. 74% female Race not reported LBP alone 78% vs. 78% vs. 70%; LBP + sciatica 22% vs. 22% vs. 30% Use of pharmacologic treatments 65% vs. 69% vs. 67%
Shimoji 2007	Single-center Japan	Chronic back pain outpatients with or without osteoarthritis Excluded: inability to attend sessions, use of analgesics	Randomized: 21 Analyzed: 21 Attrition: 0% (0/21)	A. Active TENS + massage twice a week for 5 weeks (n=11) B. Sham TENS + massage twice a week for 5 weeks (n=10)	A vs. B Mean age 62 vs. 64 years 18% vs. 20% female Race not reported Spondylosis deformans 82% vs. 80% Mean NRS 4.5 vs. 5.0

Appendix E44. Data Abstraction of Randomized Controlled Trials of TENS

Author, Year	Duration of Pain (acute, subacute, chronic)	Outcome Measures	Duration of Followup	Results (list results for acute, subacute and chronic separately)
Buchmuller 2012	Chronic: 40 vs. 35 months	Improvement of ≥50% in VAS from baseline Improvement in Roland-Morris disability questionnaire Quality of life, SF-36 Dallas functional repercussion of pain score (scale 0-100) Patient satisfaction (scale 0%-100%)	3 months	A vs. B Improvement of ≥50% in lumbar pain VAS from baseline: 25% (26/104) vs. 7% (7/104); RR 3.71 (95% CI 1.69 to 8.18) Improvement of ≥50% in radicular pain VAS from baseline: 34% (22/65) vs. 15% (9/60); RR 2.26 (95% CI 1.13 to 4.51) Improvement on Roland-Morris disability questionnaire at 6 weeks: 30% (32/107) vs. 24% (28/115); RR 1.23 (95% CI 0.80 to 1.89) Improvement on Roland-Morris disability questionnaire at 3 months: 26% (29/110) vs. 25% (28/112); RR 1.05 (95% CI 0.67 to 1.65) Dallas functional repercussion of pain score, everyday activities: 69 vs. 69; p=0.84 Dallas functional repercussion of pain score, professional and leisure activities: 70 vs. 70; p=0.98 Dallas functional repercussion of pain score, anxiety and depression: 43 vs. 43; p=0.95 Dallas functional repercussion of pain score, sociability: 30 vs. 35; p=0.80 SF-36 physical dimensions score: 35.3 vs. 34.4; p=0.22 SF-36 psychological dimensions score: 39.3 vs. 39.1; p=0.96 Patient satisfaction scale >50% at 6 weeks: 53% (51/96) vs. 57% (55/96); RR 0.93 (95% CI 0.72 to 1.20) Patient satisfaction scale >50% at 3 months: 62% (53/86) vs. 57% (43/75); RR 1.07 (95% CI 0.83 to 1.39)
Facci 2011	Chronic: 3 to 6 months 16% vs. 14% vs. 20%; 6 to 12 months 18% vs. 16% vs. 14%; >12 months 66% vs. 70% vs. 66%	Pain: VAS; McGill Pain Questionnaire Change in Roland Morris Disability Questionnaire (RMDQ)	2 weeks	A vs. B vs. C VAS, mean change from baseline: -3.91 vs. -4.48 vs. -0.85; A vs. B, p=NS; A vs. C and B vs. C p>0.05 McGill pain intensity index, mean change from baseline: -1.45 vs. -1.41 vs. -0.66; A vs. B, p=NS; A vs. C and B vs. C p>0.05 McGill pain rating index, mean change from baseline: -17.66 vs. -25.34 vs. -3.53; A vs. B p>0.05; A vs. C and B vs. C p>0.05 McGill number of words describing pain, mean change from baseline: -6.80 vs. -8.30 vs. -0.12; A vs. B, p=NS; A vs. C and B vs. C p>0.05 RMDQ, mean change from baseline (scores approximated based on graphic description): -6.26 vs. -7.42 vs. -0.91; A vs. B, p=NS; A vs. C and B vs. C p>0.05
Shimoji 2007	Chronic: 2.5 vs. 2.8 months	Pain: NRS, scale 0-10	6 weeks	A vs. B Pain, mean change from baseline: -1.4 vs. -1.1; p=0.4

Appendix E44. Data Abstraction of Randomized Controlled Trials of TENS

Author, Year	Adverse Events Including Withdrawals	Funding Source	Quality Rating	Comments
Buchmuller 2012	A vs. B Withdrawals: 22% (26/117) vs. 30% (36/119); RR 0.73 (95% CI 0.48 to 1.14) Withdrawals due to adverse events: 3% (3/117) vs. 0.8% (1/119); RR 3.05 (95% CI 0.32 to 29) Serious adverse events: 4% (5/117) vs. 6% (7/119); RR 0.73 (95% CI 0.24 to 2.22) TENS application site skin reaction: 9% (11/117) vs. 3% (3/119); RR 3.73 (95% CI 1.07 to 13)	French Ministere de la Sante et Sports; Fondation CNP Assurances; Institut UPSA Douleurs; CEFAR France	Fair	
Facci 2011	None reported	None reported	Good	p values not reported but narratively described as significant or not significant
Shimoji 2007	None reported	Omron Healthcare	Fair	

Please see Appendix C. Included Studies for full study references.

Appendix E45. Data Abstraction of Randomized Controlled Trials of Electrical Stimulation

Author, Year	Country Number of Centers and Setting	Inclusion Criteria	Number Randomized, Analyzed Attrition	Intervention
Durmus, 2009	Turkey Single center	Low back pain for >3 months, female Exclude: Acute radicular signs or symptoms, radiographic evidence of inflammatory spinal disease, tumor, spondylolysis, spondylolisthesis, sacroiliitis, serious medical conditions, neuromuscular or dermatological disease of the lumbar and abdominal areas, recent exercise program, pacemaker or defibrillator, contracture, previous trauma	Randomized: 41 Analyzed: Unclear Attrition: Not reported	A: Electrical muscle stimulation + exercise: Applied at L2-L4 levels over erector spinae muscles bulks motor points when prone (15 minutes) and obliquus externus abdominus muscles motor points when supine (15 minutes), symmetric biphasic wave at 50 Hz and 50 ms phase time, intensity increased until apparent muscle contraction established (70-120 mA), applied for 10 s of contraction and 10 s of relaxation; 30 minutes 3 times weekly for 8 weeks plus exercise (see below) (n=21) B: Exercise: Group exercise 20 minute back and abdominal exercises and 5 minute stretching 3 times a week for 8 weeks; also given an exercise program consisting of six exercises (n=20)
Durmus, 2010	Turkey Single center	Low back pain for >3 months, female Exclude: Acute radicular signs or symptoms, radiographic evidence of inflammatory spinal disease, tumor, spondylolysis, spondylolisthesis, sacroiliitis, serious medical conditions, neuromuscular or dermatological disease of the lumbar and abdominal areas, recent exercise program, pacemaker or defibrillator, contracture, previous trauma, severe structural deformity, previous spinal surgery, pregnant	Randomized: 68 Analyzed: 59 Attrition: 13% (9/68) at 6 weeks	A: Electrical muscle stimulation + exercise: Applied at L2-L4 levels over erector spinae muscles bulks motor points when prone (15 minutes), symmetric biphasic wave at 50 Hz and 50 ms phase time, intensity increased until apparent muscle contraction established (60-130 mA), applied for 10 s of contraction and 10 s of relaxation; 15 minutes 3 times weekly for 6 weeks + exercise (see below) (n=20) B: Ultrasound + exercise: 1 MHz at 1 W/cm^2, applied for 10 minutes 3 times a week for 6 week + exercise (see below) (n=19) C: Exercise: 45 minute back and abdominal exercises and 5 minute stretching 3 times a week for 6 weeks; also given an exercise program consisting of four exercises (n=20)

Appendix E45. Data Abstraction of Randomized Controlled Trials of Electrical Stimulation

Author, Year	Study Participants	Duration of Pain (acute, subacute, chronic)	Outcome Measures	Duration of Followup
Durmus, 2009	A vs B Mean age: 47 vs. 43 years Female: 100% vs. 100% Race: Not reported Pain intensity (mean, 0-10 VAS): 7.9 vs. 7.5 ODI (mean, 0-100): 37 vs. 37	All chronic, mean duration 6.5 vs. 8.8 years		8 weeks (at end of therapy)

Appendix E45. Data Abstraction of Randomized Controlled Trials of Electrical Stimulation

Durmus, 2010	A vs B Mean age: 49 vs. 48 vs. 47 years Female: 100% vs. 100% vs. 100% Race: Not reported Pain intensity (median, 0-10 VAS): 4.9 vs. 3.9 vs. 2.4 ODI (mean, 0-100): 28 vs. 26 vs. 26	All chronic, mean duration 11 vs. 11 vs. 11 years		6 weeks (at end of therapy)

Appendix E45. Data Abstraction of Randomized Controlled Trials of Electrical Stimulation

Author, Year	Results (list results for acute, subacute, and chronic separately)	Adverse Events Including Withdrawals	Funding Source	Quality (Cochrane Back Group)	Comments
Durmus, 2009	A vs B Pain (mean, 0-10 VAS, estimated from graph): 4.9 vs. 5.8 at 2 w, 2.9 vs. 4.8 at 4 w, 0.9 vs. 3.8 at 8 w (p not reported and not estimable) ODI (mean, 0-100): 6.6 vs. 19.2 at 8 w (p=0.001) Pain Disability Index (median, 0-50): 4 vs. 9.5 at 8 w (p=0.01) Beck Depression Inventory (mean, 0-63): 2.8 vs. 3.3 at 8 w (p>0.05) SF-36 Physical Function (mean, 0-100): 92 vs. 73 at 8 w (p=0.001) SF-36 Mental Health (mean): 82 vs. 70 at 8 w (p=0.006) SF-36 Pain (mean): 87 vs. 64 at 8 w (p=0.001) SF-36 General health (mean): 76 vs. 64 at 8 w (p=0.01) SF-36 Social function (median): 55 vs. 44 at 8 w (p>0.05) SF-36 Physical role limitations (median): 100 vs. 65 at 8 w (p=0.001) SF-36 Emotional role limitations (median): 100 vs. 82 at 8 w (p=0.01) SF-36 Energy (median): 85 vs. 70 at 8 w (p=0.001)	Not reported	Not reported	Poor	

Durmus, 2010	A vs B Pain (mean, 0-10 VAS, estimated from graph): 2.9 vs. 2.9 vs. 3.9 at 3 w, 0.4 vs. 0.9 vs. 2.4 at 6 w (p<0.05 for A or B vs. C) ODI (mean, 0-100): 6.80 vs. 8.69 vs. 8.40 at 6 w (p=0.07) Pain Disability Index (median, 0-50): 5.15 vs. 6.21 vs. 6.50 at 6 w (p=0.62) Beck Depression Inventory (mean, 0-63): 3.35 vs. 3.94 vs. 4.85 at 6 w (p=0.37) SF-36 Physical Function (mean, 0-100): 97.5 vs. 90.0 vs. 90.0 at 6 w (p=0.009) SF-36 Mental Health (mean): 78.7 vs. 73.0 vs. 71.8 at 6 w (p=0.17) SF-36 Pain (median): 88.0 vs. 88.0 vs. 77.0 at 6 w (p=0.28) SF-36 General health (mean): 70.4 vs. 65.5 vs. 64.2 at 6 w (p=0.23) SF-36 Social function (median): 88.0 vs. 77.0 vs. 77.0 at 6 w (p=0.02) SF-36 Physical role limitations (median): 100 vs. 100 vs. 100 at 6 w (p=0.30) SF-36 Emotional role limitations (median): 100 vs. 100 vs. 100 at 6 w (p=0.58) SF-36 Energy (median): 83.8 vs. 68.7 vs. 67.8 at 6 w (p=0.001)	Not reported	Not reported	Poor	

Appendix E45. Data Abstraction of Randomized Controlled Trials of Electrical Stimulation

Author, Year	Country Number of Centers and Setting	Inclusion Criteria	Number Randomized, Analyzed Attrition	Intervention
Glazer, 2001	United States Single center	18 to 60 years of age, LBP ≥6 months, LBP greater than radicular pain Exclude: Prior electrical stimulation treatment (including TENS), pregnant, morbid obesity, nonspinal cause of low back pain, end-stage or terminal medical problem	Randomized: 80 Analyzed: 55 at 2 m, 38 at 6 m Attrition: 31% (25/80) at 2 m, 52% (42/80) at 6 m	A: Electrical muscle stimulation + exercise: Placed on lower back, parameters not reported + exercise (see below), 30 minutes 2 times daily for 2 months (n=32) B: Sham stimulation + exercise: Group instruction on strength and flexibility exercises, 3 sessions once weekly for 3 weeks and instructed to perform home exercises for 6 months (n=23)

Appendix E45. Data Abstraction of Randomized Controlled Trials of Electrical Stimulation

Moore, 1997	United States Single center	Back pain for ≥6 months largely unresponsive to previous treatments Exclude: Pregnancy, cardiac pacemaker, serious psychological disorder, previous treatment with TENS or electrical muscle stimulation	Randomized: 28 Analyzed: 24 Attrition: 14% (4/28) prior to completion of trial (4 crossover periods of 2 days each with 2 day hiatus)	A: Electrical muscle stimulation: Location not specified, symmetric biphasic wave at 70 Hz and 200 ms pulse width, amplitude adjustable from 0 to 100 mA to produce muscle contractions, cycle on-time 5 seconds and off-time 15 seconds; three 10 minute periods of stimulation alternating with 130 minute periods of no treatment B: TENS: Asymmetrical biphasic square pulse, 100 Hz and 100 ms pulse width, amplitude 0 to 60 mA C: Electrical muscle stimulation + TENS: Alternating one 10 minute and one 20 minute period of electrical muscle stimulation with 3 periods of TENS stimulation D: Sham TENS Crossover design (n=24), each intervention 5 hours/day for 2 days, with 2 day hiatus between interventions

Appendix E45. Data Abstraction of Randomized Controlled Trials of Electrical Stimulation

Author, Year	Study Participants	Duration of Pain (acute, subacute, chronic)	Outcome Measures	Duration of Followup
Glazer, 2001	Mean age: 51 vs. 53 years Female: 62% vs. 52% Non-white race: 30% vs. 32% Pain: Not reported Back-specific function: Not reported	All chronic, mean duration not reported		6 months (4 months after completion of stimulation intervention)

Appendix E45. Data Abstraction of Randomized Controlled Trials of Electrical Stimulation

Moore, 1997	Mean age: 52 years Female: 67% Race: Not reported Pain intensity: 49 vs. 46 vs. 48 vs. 51 Back-specific function: Not reported Conditions: 9 bulging disc, 7 postlaminectomy, 5 spinal stenosis, 1 spondylolisthesis; 15 low back pain, 3 middle back pain 4 upper back pain, 2 diffuse back pain	All chronic; mean 3.8 years		Assessed after 2 days of each intervention

Appendix E45. Data Abstraction of Randomized Controlled Trials of Electrical Stimulation

Author, Year	Results (list results for acute, subacute, and chronic separately)	Adverse Events Including Withdrawals	Funding Source	Quality (Cochrane Back Group)	Comments
Glazer, 2001	A vs. B Low Back Pain Outcome Instrument Job Exertion (mean, 1-6): 2.69 vs. 2.83 at 2 m, 2.74 vs. 2.89 at 6 m LBPOI Job Stress/Satisfaction (mean, 1-6): 3.20 vs. 2.25 at 2 m, 3.02 vs. 2.44 at 6 m LBPOI Back Pain/Disability (mean, 1-6): 2.36 vs. 2.13 at 2 m, 2.45 vs. 2.30 at 6 m LBPOI Neurogenic Symptoms (mean, 1-6): 1.92 vs. 1.87 at 2 m, 2.17 vs. 1.89 at 6 m LBPOI Expectations Met (mean, 1-6): 4.21 vs. 3.79 at 2 m, 4.02 vs. 3.72 at 6 m SF-36 Mental health (mean, 0-100): 70 .2 vs. 80.0 at 2 m, 67.9 vs. 76.2 at 6 m	Not reported	Not reported	Poor	Some differences on LBPOI subscales reported as statistically significant, but does not appear to be possible based on reported point estimates and standard deviations

Appendix E45. Data Abstraction of Randomized Controlled Trials of Electrical Stimulation

Moore, 1997	A vs. B vs. C vs. D Pain (mean, 0-100 VAS): 39.7 vs. 40.6 vs. 36.3 vs. 44.8 (p>0.05 for overall effect, but p=0.02 for C vs. D) Present Pain Intensity (mean, 0-4): 2.21 vs. 2.27 vs. 1.94 vs. 2.42 (p=0.03 for overall effect, p<0.02 for C vs. A, B, or D)	"No adverse treatment effects were reported"	Not reported	Poor	

Appendix E45. Data Abstraction of Randomized Controlled Trials of Electrical Stimulation

Author, Year	Country Number of Centers and Setting	Inclusion Criteria	Number Randomized, Analyzed Attrition	Intervention
Pope, 1994	United States Single center	18 to 55 years of age, low back pain for 3 weeks to 6 months Exclude: Pregnant, sciatica, neurologic deficits, prior vertebral fracture, tumor, infection, or spondyloarthropathy, prior back surgery, BMI >33, prior manipulation for current episode, pacemaker, workmen's compensation or disability insurance issues	Randomized: 164 Analyzed: Unclear Attrition: 12% did not complete baseline and week 3 evaluations	A: Electrical muscle stimulation: Applied to painful back on back, symmetric biphasic wave at 37 Hz and 225 ms pulse width, amplitude adjustable from 0 to 91 mA to produce muscle contractions, pulse ramped up for 2 seconds, held for 6 seconds, ramped off for 2 seconds, 6 second pause; used for at least 8 hours per day for 3 weeks (n=28) B: Manipulation: Dynamic short lever, high velocity, low amplitude thrust exerting force on the lumbar spine and/or sacroiliac joint, unilaterally or bilaterally as determined by treating physicians, 3 sessions per week for 3 weeks (n=70) C: Massage: Effleurage massage for up to 15 minutes, 3 sessions per week for 3 weeks (n=37) D: Lumbar support: Freeman Lumbosacral Corset to be worn during waking hours except while bathing, could be removed up to 10 minutes up to 3 times daily (n=29)

Appendix E45. Data Abstraction of Randomized Controlled Trials of Electrical Stimulation

Author, Year	Study Participants	Duration of Pain (acute, subacute, chronic)	Outcome Measures	Duration of Followup
Pope, 1994	Age: Not reported Sex: Not reported Race: Not reported Pain intensity: States no statistically significant differences, data not reported Back-specific function: Not reported	3 weeks to 6 months; mean duration not reported		3 weeks (at end of treatment)

Appendix E45. Data Abstraction of Randomized Controlled Trials of Electrical Stimulation

Author, Year	Results (list results for acute, subacute, and chronic separately)	Adverse Events Including Withdrawals	Funding Source	Quality (Cochrane Back Group)	Comments
Pope, 1994	A vs B vs C vs D Pain (mean change from baseline, 0-100 VAS): -9.6 vs. -24 vs. -17 vs. -16 (p>0.05 for all between-group comparisons)	Not reported	Foundation for Chiropractic Research and Education	Fair	

Please see Appendix C. Included Studies for full study references.

Appendix E46. Trials of PENS Included in the APS/ACP Review

Author, Year, Title	Purpose of Study	Study Design	Inclusion Criteria	Exclusion Criteria	Number of Treatment and Control Subjects (number approached, number eligible, number enrolled)
Ghoname, 1999 Percutaneous electrical nerve stimulation: an alternative to TENS in the management of sciatica	To evaluate the efficacy of PENS relative to TENS, sham PENS, and exercise therapy in patients with sciatica	RCT	Age >18 years, history of sciatica, absence of major co morbid illness, stable LBP for at least 6 weeks	Drug or alcohol abuse, change in pain within 6 weeks	Number approached and eligible not reported 64 randomized (initial allocation groups not reported)
Ghonome, 1999 Percutaneous electrical nerve stimulation for low back pain	To evaluate the efficacy of PENS relative to TENS, sham PENS, and exercise therapy in patients with chronic low back pain	RCT	Age >18 years, radiologically confirmed degenerative disc disease, absence of major co morbid illness, stable LBP for at least 3 months	Drug or alcohol abuse, long-term opioids use, change in pain within 3 months, sciatica, previous use of nontraditional therapies, pending litigation	Number approached and eligible not reported 60 randomized (initial allocation groups not reported)

Appendix E46. Trials of PENS Included in the APS/ACP Review

Author, Year, Title	Subject Age, Gender, Diagnosis	Country and Setting	Sponsor	Measures
Ghoname, 1999 Percutaneous electrical nerve stimulation: an alternative to TENS in the management of sciatica	Demographics not reported by initial allocated groups Mean age: 43 years Female gender: 53% nonwhite race: Not reported Duration of pain: Mean 21 months Baseline pain before starting each treatment: 7.6	US Single center Pain clinic	Not reported	SF-36 Physical Component Summary and Mental Component Summary Pain: VAS (0-10 cm) Activity : VAS (0-10) Quality of sleep: VAS (0-10)
Ghonome, 1999 Percutaneous electrical nerve stimulation for low back pain	Demographics not reported by initial allocated groups Mean age: 43 years Female gender: 52% nonwhite race: Not reported Duration of pain: Not reported Baseline pain before starting each treatment: 6.3 vs. 6.2 vs. 6.5 vs. 5.7	US Single center Pain clinic	Ambulatory Anesthesia Research Foundation of Dallas, Forest Park Institute for Pain Management	SF-36 Physical Component Summary and Mental Component Summary Pain: VAS (0-10 cm) Activity : VAS (0-10) Quality of sleep: VAS (0-10)

Appendix E46. Trials of PENS Included in the APS/ACP Review

Author, Year, Title	Type of Intervention	Results	Duration of Followup
Ghoname, 1999 Percutaneous electrical nerve stimulation: an alternative to TENS in the management of sciatica	A: PENS with stimulation started at 4 Hz and adjusted as tolerated 3 times/week B: TENS 3 times/week C: Sham-PENS (needle insertion without electrical current) Each intervention for 3 weeks, 1 week washout, then crossover	PENS vs. TENS vs. sham PENS Pain (VAS 0 to 10), improvement from baseline: -3.1 vs. -2.6 vs. -0.5 (p<0.01 for PENS vs. other interventions) Level of activity (0 to 10), improvement from baseline: -2.4 vs. -1.3 vs. -0.5 (p<0.01 for PENS vs. other interventions) Quality of sleep (0 to 10), improvement from baseline: -2.4 vs. -1.0 vs. -0.3 (p<0.01 for PENS vs. other interventions) SF-36 Physical component summary, mean improvement from baseline in PENS group relative to comparison interventions: +5.7 vs. +6.9 (PENS superior, p<0.05) SF-36 Mental component summary, mean improvement from baseline in PENS group relative to comparison interventions: +2.1 vs. +2.5 (PENS superior, p<0.05)	At end of each 3-week course of treatment
Ghonome, 1999 Percutaneous electrical nerve stimulation for low back pain	A: PENS with stimulation started at 4 Hz and adjusted as tolerated 3 times/week B: TENS 3 times/week C: Exercise with spine flexion and extension D: Sham-PENS (needle insertion without electrical current) Each intervention for 3 weeks, 1 week washout, then crossover	PENS vs. TENS vs. exercise vs. sham PENS Pain (VAS 0 to 10), improvement from baseline: -2.9 vs. -0.6 vs. -0.1 vs. -0.2 (p<0.02 for PENS vs. other interventions) Level of activity (0 to 10), improvement from baseline: -2.3 vs. -0.8 vs. 0 vs. -0.2 (p<0.02 for PENS vs. other interventions) Quality of sleep (0 to 10), improvement from baseline: -2.4 vs. -0.3 vs. -0.3 vs. 0 (p<0.02 for PENS vs. other interventions) SF-36 Physical component summary, mean improvement from baseline in PENS group relative to comparison interventions: +4.66 vs. +5.82 vs. +4.97 (PENS superior, p<0.05) SF-36 Mental component summary, mean improvement from baseline in PENS group relative to comparison interventions: +1.7 vs. +1.84 vs. +1.84 (PENS superior, p<0.05)	At end of each 2-week intervention period

Appendix E46. Trials of PENS Included in the APS/ACP Review

Author, Year, Title	Loss to Followup	Compliance to Treatment	Adverse Events and Withdrawals Due To Adverse Events	Quality Rating	Comments
Ghoname, 1999 Percutaneous electrical nerve stimulation: an alternative to TENS in the management of sciatica	Not reported	Not reported	Not reported		
Ghonome, 1999 Percutaneous electrical nerve stimulation for low back pain	Not reported	Not reported	Not reported		Minimal exercise program

Appendix E46. Trials of PENS Included in the APS/ACP Review

Author, Year, Title	Purpose of Study	Study Design	Inclusion Criteria	Exclusion Criteria	Number of Treatment and Control Subjects (number approached, number eligible, number enrolled)
Weiner, 2003 Efficacy of percutaneous electrical nerve stimulation for the treatment of chronic low back pain in older adults	To evaluate the efficacy of PENS versus sham therapy in patients with chronic low back pain	RCT	65 or older, low back pain for the last 3 months	Prominent radicular component, pacemaker, anticoagulation, known spinal pathology other than osteoarthritis, active nonmusculoskeletal pain or lumbosacral pain interfering with activity, neurologic disorder, heavy alcohol use, conditions making repetitive lifting unsafe	Number approached and eligible not reported 34 randomized (17 to PENS, 17 to sham PENS)
Yokoyama, 2004 Comparison of percutaneous electrical nerve stimulation with transcutaneous electrical nerve stimulation for long-term pain relief in patients with chronic low back pain	To evaluate the efficacy of one PENS treatment relative to TENS in patients with chronic low back pain	RCT	Low back pain >6 months, peak pain >40 on 0 to 100 scale, pain intensity stable with NSAIDs for at least 3 months	Prior PENS, pregnancy, osteomyelitis, discitis, tumor, ankylosing spondylitis, recent vertebral fracture, structural scoliosis, or previous low back surgery	Number approached and eligible not reported 60 randomized (20 to PENS, 20 to PENS followed by TENS, and 20 to TENS)

Appendix E46. Trials of PENS Included in the APS/ACP Review

Author, Year, Title	Subject Age, Gender, Diagnosis	Country and Setting	Sponsor	Measures
Weiner, 2003 Efficacy of percutaneous electrical nerve stimulation for the treatment of chronic low back pain in older adults	Mean age: 74 vs. 74 Female gender: 65% vs. 41% nonwhite race: 6% vs. 0% Duration of pain: 10.6 vs. 16.6 years Baseline MPI Pain severity: 3.21 vs. 3.28	US Single center Geriatric clinic	US Public Health Service	McGill Pain Questionnaire Multidimensional Pain Inventory Pain Severity Scale Roland Morris Back Pain disability Questionnaire Multidimensional Pain Inventory Pain Interference Scale Physical performance Geriatric Depression Scale Pittsburgh Sleep Quality Index Mini-mental status examination Medication use
Yokoyama, 2004 Comparison of percutaneous electrical nerve stimulation with transcutaneous electrical nerve stimulation for long-term pain relief in patients with chronic low back pain	Mean age: 60 vs. 58 vs. 59 Female gender: 61% vs. 53% vs. 56% nonwhite race: Not reported (study conducted in Japan) Duration of pain: 15 vs. 15 vs. 13 months Baseline pain score (0 to 100 scale): 55 vs. 56 vs. 57	Japan Single center Anesthesia clinic	Not reported	Pain: VAS (0 to 100) Physician assessment of impairment: 0 (none) to 4 (severely limited) Intake of NSAIDs

Appendix E46. Trials of PENS Included in the APS/ACP Review

Author, Year, Title	Type of Intervention	Results	Duration of Followup
Weiner, 2003 Efficacy of percutaneous electrical nerve stimulation for the treatment of chronic low back pain in older adults	A: PENS with increasing stimulation frequencies per protocol, twice a week for 6 weeks + physical therapy B: Sham PENS (insertion of needles without electrical stimulation) + physical therapy	PENS + physical therapy versus sham PENS + physical therapy (mean scores 3 months after treatment) McGill Pain Questionnaire: 6.19 vs. 11.82 (p=0.04) Multidimensional Pain Inventory Pain Inventory score: 2.16 vs. 3.10 (p=0.003) Roland Disability scale: 9.25 vs. 12.18 (p=0.26) MPI Pain Interference Scale: 2.61 vs. 2.97 (p=0.57) Geriatric Depression Scale: 4.11 vs. 5.41 (p=0.75)	3 months after treatment
Yokoyama, 2004 Comparison of percutaneous electrical nerve stimulation with transcutaneous electrical nerve stimulation for long-term pain relief in patients with chronic low back pain	A: PENS with stimulation started at 4/30 Hz and adjusted as tolerated twice weekly for 8 weeks B: PENS for 4 weeks, then TENS for 4 weeks C: TENS twice weekly for 8 weeks	PENS vs. TENS Pain (VAS pain scores): 32 vs. 48 at week 8 (p<0.01), returned to baseline in PENS group at week 16 (2 months after treatment) Physical impairment (0 to 4 scale): difference between PENS and TENS significant at end of treatment but not 1 month after treatment NSAID use: No differences two months after treatment	2 months after treatment

Appendix E46. Trials of PENS Included in the APS/ACP Review

Author, Year, Title	Loss to Followup	Compliance to Treatment	Adverse Events and Withdrawals Due To Adverse Events	Quality Rating	Comments
Weiner, 2003 Efficacy of percutaneous electrical nerve stimulation for the treatment of chronic low back pain in older adults	Not reported	Not reported	Not reported		
Yokoyama, 2004 Comparison of percutaneous electrical nerve stimulation with transcutaneous electrical nerve stimulation for long-term pain relief in patients with chronic low back pain	6/60 (10%)	Not reported	Not reported		

Please see Appendix C. Included Studies for full study references.

Appendix E47. Data Abstraction of Randomized Controlled Trials of PENS

Author, Year	Country Number of Centers and Setting	Inclusion Criteria	Number Randomized, Analyzed Attrition	Intervention
Hamza, 1999	USA Single center	>18 years of age, low back pain with radiologically confirmed degenerative lumbar disc disease, pain level stable for ≥3 months Exclude: Radicular component, history of drug or alcohol abuse, previous acupuncture, recent change in analgesic medications or use of opioids	Number randomized: 75 Analyzed: Unclear Attrition: Not reported	A: PENS: 10 32-gauge needles placed into low back pain to depth of 2-4 cm in a dermatomal (or sclerotomal) distribution of pain for 60 minutes; connected to bipolar leads at alternating frequency of 15 and 30 Hz for 45 minutes (maximum amplitude 25 mA using unipolar square-wave pattern and pulse width of 0.5 ms) B: PENS: Stimulation for 30 minutes C: PENS: Stimulation for 15 minutes D: PENS: Stimulation for 0 minutes Crossover design, each intervention administered 3 times a week for 2 weeks, with 1 week between treatments (total 11 weeks)
Pérez-Palomares, 2010	Spain Single center	>18 years of age, non-radicular low back pain ≥4 months or shorter duration if unresponsive to therapy Exclude: Fibromyalgia syndrome, structural lesions in the lumbar column, concomitant non-pharmacological treatments, co-morbid medical conditions or circumstances that might have impacted results	Number randomized: 122 Analyzed: 112 Attrition: 8.9% (10/122)	A: PENS: Eight 0.3 x 25 mm needles placed into low back pain to depth of 2-2.5 cm 8 in a dermatomal distribution, 0.3 ms impulse duration, for 30 minutes (n not reported) B: Dry needling: 0.30 x 40 mm needles inserted into trigger points using fast-in and fast-out Hong's technique, followed by spray and stretch technique (n not reported) 3 sessions weekly for total of 9 sessions over 3 weeks

Appendix E47. Data Abstraction of Randomized Controlled Trials of PENS

Author, Year	Study Participants	Duration of Pain (acute, subacute, chronic)	Outcome Measures	Duration of Followup
Hamza, 1999	Mean age: 47 years (overall) Female: Not reported Race: Not reported Baseline pain (mean, 0-10 VAS): 6.3 vs. 6.4 vs. 6.8 vs. 6.2 Baseline function: Not reported Prior surgery: 42% (overall)	All chronic (≥3 months), mean duration 38 months		2 weeks (at end of each treatment period)
Pérez-Palomares, 2010	Mean age: Not reported, 34% vs. 50% <40 years of age Female: 81% vs. 67% Race: Not reported Baseline pain (mean, 0-10 VAS): 6.27 vs. 6.04 Baseline function: Not reported	Acute to chronic; 84% vs. 74% <3 months		3 weeks (at end of therapy)

Appendix E47. Data Abstraction of Randomized Controlled Trials of PENS

Author, Year	Results (list results for acute, subacute, and chronic separately)	Adverse Events Including Withdrawals	Funding Source	Quality Rating	Comments
Hamza, 1999	A vs. B vs. C vs. D Pain (mean, 0-10 VAS): 1.5 vs. 1.6 vs. 2.0 vs. 5.4 at 2 weeks Pain (percent improvement from baseline, 0-10 VAS): 40% vs. 46% vs. 22% vs. 10% (p<0.01 for A or B vs. D and p<0.05 for C vs. D) SF-36 Physical component summary (mean improvement, 0-100): +7.1 vs. +7.4 vs. +5.4 vs. not reported (p<0.001 for A or B vs. D and p<0.01 for C vs. D) SF-36 Mental component summary (mean improvement, 0-100): +2.9 vs. +3.1 vs. +2.1 vs. not reported (p<0.001 for A or B vs. D and p<0.01 for C vs. D) Physical activity (percent improvement from baseline, 0-10 VAS): 50% vs. 53% vs. 28% vs. 8% (p<0.01 for A or B vs. D, p<0.05 for C vs. D) Sleep quality (percent improvement from baseline, 0-10 VAS): 40% vs. 44% vs. 25% vs. 5% (p<0.01 for A or B vs. D, p<0.05 for C vs. D) Use of nonopioid analgesics (percent decreased in pills per day): 35% vs. 38% vs. 21% vs. 8% (p<0.01 for A or B vs. D, p<0.05 for C vs. D)	Not reported	Forest Park Institute and Egyptian Cultural and Educational Bureau	Poor	
Pérez-Palomares, 2010	A vs. B Pain (mean difference from baseline, 0-10 VAS): 2.38 vs. 2.35 (p=0.94) >40% improvement in pain: 54% (28/52) vs. 46% (24/52), RR 1.17 (95% CI 0.79 to 1.72) Sleep quality (mean difference from baseline, 0-10 VAS): 1.72 vs. 1.85 (p=0.68) ODI Personal care (median difference from baseline, 0-1): 0.38 vs. 0.34 (p=0.94) ODI Lifting weight: 0.59 vs. 0.06 (p=0.03) ODI Walking: 0.17 vs. 0.15 (p=0.86) ODI Sitting: 0.21 vs. 0.33 (p=0.51) ODI Standing: 0.25 vs. 0.41 (p=0.26) ODI Social life: 0.72 vs. 0.72 (p=0.18)	Not reported	Not reported	Poor	

Please see Appendix C. Included Studies for full study references.

Appendix E48. Trials of Interferential Therapy Included in the APS/ACP Review

Author, Year, Title	Purpose of Study	Study Design	Inclusion Criteria	Exclusion Criteria	Number of Treatment and Control Subjects (number approached, number eligible, number enrolled)
Hurley, 2004 A randomized clinical trial of manipulative therapy and interferential therapy for acute low back pain	To evaluate the efficacy of interferential therapy versus manipulative therapy or the combination in patients with acute low back pain	RCT	Low back pain for 4 to 12 weeks with or without radiation to lower limbs, age 18 to 65	Previous spinal surgery, recent motor vehicle accident, systemic disease, concurrent medical or musculoskeletal conditions, contraindications to manipulative therapy or interferential therapy, reflex and/or motor signs of nerve root, spinal cord, or cauda equina compression, episodes of LBP In last 6 months, physiotherapy for LBP in last 12 months, psychiatric illness, Roland score <4, pregnancy	569 approached 249 enrolled (80 to interferential therapy, 80 to manipulative therapy, and 80 to combination)
Hurley, 2001 Interferential therapy electrode placement technique in acute low back pain: a preliminary investigation	To evaluate the efficacy of two different methods for placing interferential therapy electrodes to a self-care education book	RCT	Low back pain for 4 to 12 weeks with or without radiation to lower limbs, age 18 to 65	No back pain in last 6 months, breaks in skin or lack of normal skin sensation, epilepsy, pregnancy, previous spinal surgery or fracture of the vertebrae, significant co-morbid medical conditions, reflex and/or motor signs of nerve root compression	Number approached and eligible not reported 60 enrolled (18 to interferential therapy applied to painful area, 22 to interferential therapy applied lateral to spinal nerve, 20 to back book)
Werners, 1999 Randomized trial comparing interferential therapy with motorized lumbar traction and massage in the management of low back pain in a primary care setting	To evaluate the efficacy of interferential therapy versus traction in patients with low back pain of varying duration	RCT	Low back pain severe enough to warrant treatment, age 20 to 60 years	Significant medical condition, previous surgery, spinals disorder on x-ray (e.g., spondylolysis)	Number approached and eligible not reported 152 enrolled (83to interferential therapy and 78 to traction)

Appendix E48. Trials of Interferential Therapy Included in the APS/ACP Review

Author, Year, Title	Subject Age, Gender, Diagnosis	Country and Setting	Sponsor	Measures
Hurley, 2004 A randomized clinical trial of manipulative therapy and interferential therapy for acute low back pain	Mean age: 40 vs.40 vs. 40 Female gender: 62% vs. 57% vs. 60% Non-white race: Not reported Duration of pain: 7.6 vs. 7.5 vs. 8.3 weeks Baseline pain (0 to 100): 52 vs. 52 vs. 50	Ireland Multicenter Physical therapy clinics	Society of Orthopedic Medicine, Manipulation Association of Chartered Physiotherapists Churchill Livingstone Award	Pain: VAS (0 to 100) McGill Pain Questionnaire Pain Rating Index (0 to 78) EQ-5D SF-36 Roland Disability Questionnaire LBP recurrence Work absenteeism Analgesics use
Hurley, 2001 Interferential therapy electrode placement technique in acute low back pain: a preliminary investigation	Median age: 35 vs. 35 vs. 30 years Female gender: 61% vs. 39% vs. 45% Non-white race: Not reported Duration of pain: 5.0 vs. 7.0 vs. 4.0 weeks Baseline Pain Rating Index score (0 to 78): 11.5 vs. 14.0 vs. 15.5 Median Roland Disability score (0 to 24): 5.5 vs. 9.0 vs. 5.0 (p=0.156)	Ireland Single center Physical therapy clinics	Society of Orthopedic Medicine, Manipulation Association of Chartered Physiotherapists Churchill Livingstone Award	McGill Pain Questionnaire Pain Rating Index (0 to 78) EQ-5D Roland Disability Questionnaire
Werners, 1999 Randomized trial comparing interferential therapy with motorized lumbar traction and massage in the management of low back pain in a primary care setting	Mean age: 38 vs. 39 years Female gender: 43% vs. 49% Non-white race: Not reported On sick leave: 46% vs. 44% Back pain <5 years: 35% overall (similar between groups) Baseline pain (VAS): 50 vs. 51	Germany Single center Orthopedic primary care clinic	Not reported	Pain: VAS (0 to 100) Oswestry Disability Index (0 to 100)

Appendix E48. Trials of Interferential Therapy Included in the APS/ACP Review

Author, Year, Title	Type of Intervention	Results	Duration of Followup
Hurley, 2004 A randomized clinical trial of manipulative therapy and interferential therapy for acute low back pain	A: Interferential therapy B: Spinal manipulation C: Interferential therapy + spinal manipulation Total of 4 to 10 treatments over 8 weeks	Interferential therapy versus manipulative therapy versus combination, mean improvement at 12 months Pain (0 to 100 VAS): -26.5 vs. -18.2 vs. -25.7 (NS) McGill Pain Questionnaire Pain Rating Index (0 to 78): -8.3 vs. -6.4 vs. -9.2 (NS) Roland score (0 to 24): -4.9 vs. -4.7 vs. -6.5 (NS) SF-36: No differences Recurrent low back pain: 69% vs. 77% vs. 64% (NS) Absent from work >30 days: 8% vs. 12% vs. 12%	12 months
Hurley, 2001 Interferential therapy electrode placement technique in acute low back pain: a preliminary investigation	A: Interferential therapy applied to painful area + back book B: Interferential therapy applied to area of spinal nerve + back book C: Back book	Inferential therapy applied to painful area + Back Book versus interferential therapy applied to area of spinal nerve + Back Book versus Back Book alone (mean difference from baseline to 3 months) McGill Pain Questionnaire Pain Rating Index (0 to 78): +2.2 vs. -2.5 vs. -9.7 Roland Score (0 to 24): -3.5 vs. -8.0 vs. -4.0 EQ-5D: No difference Roland Score (0 to 24), median score at 3 months: 2.0 vs. 1.0 vs. 1.0	3 months
Werners, 1999 Randomized trial comparing interferential therapy with motorized lumbar traction and massage in the management of low back pain in a primary care setting	A: Interferential therapy B: Traction	Interferential therapy versus traction (mean difference from baseline to 3 months) Pain (0 to 100): -9.8 vs. -14.6 (NS) Oswestry (0 to 100): -7.7 vs. -7.4	3 months

Appendix E48. Trials of Interferential Therapy Included in the APS/ACP Review

Author, Year, Title	Loss to Followup	Compliance to Treatment	Adverse Events and Withdrawals Due To Adverse Events	Quality Rating	Comments
Hurley, 2004 A randomized clinical trial of manipulative therapy and interferential therapy for acute low back pain	71% at 6 months, 67% at 12 months	234/240 received as allocated, 15% noncompliant with protocol	None reported		
Hurley, 2001 Interferential therapy electrode placement technique in acute low back pain: a preliminary investigation	1/60 (1.7%)	Average sessions 3 vs. 4 vs. 3	Not assessed		
Werners, 1999 Randomized trial comparing interferential therapy with motorized lumbar traction and massage in the management of low back pain in a primary care setting	20/148 (14%) and 81/148 (55%) had no Oswestry data and Pain data at 3 months	Not reported	Not assessed		

Please see Appendix C. Included Studies for full study references.

Appendix E49. Data Abstraction of Randomized Controlled Trials of Interferential Therapy

Author, Year	Country Number of Centers and Setting	Inclusion Criteria	Number Randomized, Analyzed Attrition	Intervention
Lara-Palomo, 2012	Spain Single center	Nonspecific low back pain ≥3 months, 18 to 65 years of age, RDQ ≥4, unable to achieve lumbar muscle flexion-relaxation in trunk flexion Exclude: Undergoing other physical therapy treatment; presence of lumbar stenosis, fibromyalgia, or spondylolisthesis; history of spinal surgery or neuromuscular kinesi tape therapy; received corticosteroids in past 2 weeks; disease of central or peripheral nervous system	Number randomized: 62 Number analyzed: 61 Attrition: 1.6% (1/62) at 10 weeks	A: Interferential therapy: Bipolar current, carrier frequency 4000 Hz at constant voltage and amplitude modulation 80 Hz, applied to lumbar area for 30 minutes at 30-50 mA, 20 sessions over 10 weeks (n=31) B: Superficial massage: Effleurage, superficial pressure, and skin rolling on the lower back for 20 minutes, 20 sessions over 10 weeks (n=31)

Appendix E49. Data Abstraction of Randomized Controlled Trials of Interferential Therapy

Author, Year	Study Participants	Duration of Pain (acute, subacute, chronic)	Outcome Measures	Duration of Followup
Lara-Palomo, 2012	Mean age: 50 vs. 47 years Female: 70% vs. 65% Race: Not reported Baseline pain (mean, 0-10 VAS): 6.67 vs. 6.52 Baseline ODI (mean, 0-100): 36.07 vs. 37.94	All chronic (≥ 3 months), mean duration not reported		10 weeks (at end of therapy)

Appendix E49. Data Abstraction of Randomized Controlled Trials of Interferential Therapy

Author, Year	Results (list results for acute, subacute, and chronic separately)	Adverse Events Including Withdrawals	Funding Source	Quality Rating	Comments
Lara-Palomo, 2012	A vs. B, mean difference in change from baseline at 10 weeks Pain (0-10 VAS): -1.06 (95% CI -1.91 to -0.22) ODI (0-100): -5.20 (95% CI -10.82 to 0.42) RDQ (0-24): -3.01 (95% CI -4.53 to -1.47) SF-36 Physical function (0-100): 5.57 (95% CI -2.27 to 13.41) SF-36 Physical role (0-100): 7.02 (95% CI 1.05 to 12.98) SF-36 Body pain (0-100): 4.72 (95% CI -0.28 to 9.71) SF-36 General health (0-100): 1.09 (95% CI -3.22 to 5.41) SF-36 Vitality (0-100): 2.04 (95% CI -3.36 to 7.43) SF-36 Social functioning (0-100): 1.14 (95% CI -3.88 to 6.15) SF-36 Mental health (0-100): 2.37 (95% CI -3.39 to 8.14) SF-36 Emotional role (0-100): 3.27 (95% CI -1.58 to 8.12) RDQ worsened by >2.5 points: 10% (3/30) vs. 13% (4/31), RR 0.78 (95% CI 0.19 to 3.18)	Not reported	Reports no funding	Fair	

Please see Appendix C. Included Studies for full study references.

Appendix E50. Trials of Superficial Heat-Cold Included in the APS/ACP Review

Author, Year, Title	Purpose of Study	Study Design	Inclusion Criteria	Exclusion Criteria	Number of Treatment and Control Subjects (number approached, number eligible, number enrolled)
Landen, 1967 Heat or cold for the relief of low back pain?	To evaluate the use of heat and cold in the symptomatic relief of nonspecific low back pain	Prospective	Chief compliant of LBP	Diagnosis of herniated disc	143 approached and enrolled (data not clear) 59 cold treatment (27 acute, 21 subacute, 11 chronic) 58 hot treatment (26 acute, 18 subacute, 14 chronic)
Mayer, 2005 Treating acute low back pain with continuous low-level heat wrap therapy and/or exercise: a randomized controlled trial	To evaluate the efficacy of combining continuous low-level wrap therapy with directional preference-based exercise on the functional ability of patients with acute low back pain	Prospective, randomized, controlled parallel study at 3 sites			Number approached and eligible not reported. 100 enrolled: heat wrap - 25 exercise - 25 heat + exercise - 24 control - 26

Appendix E50. Trials of Superficial Heat-Cold Included in the APS/ACP Review

Author, Year, Title	Subject Age, Gender, Diagnosis	Country and Setting	Sponsor	Measures
Landen, 1967 Heat or cold for the relief of low back pain?	Age and gender not reported. Chief complaint: LBP	Germany US Army General Hospital patients in Orthopedic Service care	Not reported	Recorded on data sheet: Method of injury Presence of muscle spasm or radiating pain Treatment given including progression of exercise form gluteal setting to flexion Response to treatment recorded daily on chart including increase or decrease in pain or muscle spasm. Length of hospital stay
Mayer, 2005 Treating acute low back pain with continuous low-level heat wrap therapy and/or exercise: a randomized controlled trial	Mean age 31.2 $\pm$ 10.6 years 71% female Atraumatic low back pain > 2 days and < 3 months duration, with at least a 2 month pain-free period before current episode. Pain intensity $\geq$ moderate.	USA 3 outpatient medical facilities	Proctor and Gamble. 1 author an employee of Proctor and Gamble.	Multidimensional Task Ability Profile (MTAP) questionnaire: self-report assessment functional ability - 111 common physical tasks ranked on 6-point scale. Administered 2 x at baseline (current and preinjury status). Roland-Morris Disability Questionnaire (RMDQ): assessed disability 6-point verbal rating scale to assess pain relief All measurements administered at baseline and Days 2, 4 and 7

Appendix E50. Trials of Superficial Heat-Cold Included in the APS/ACP Review

Author, Year, Title	Type of Intervention	Results
Landen, 1967 Heat or cold for the relief of low back pain?	Evaluation in physical therapy followed by classification as acute (< 48 hours after symptom onset), subacute (3 -14 days post-onset), chronic (>14 days post-onset). Patients assigned to ice or heat treatment on alternating basis. Treatment 2x/day for 20 minutes in morning and evening. Patient in prone position with pillow under hips. A) 2 hot packs placed across lumbosacral area B) Large ice cubes moved slowly over lumbosacral area until numbing occurred (usually 10-12 minutes). All patients had flexion exercises and beds were maintained in a flexion position.	Ice vs. heat Length of hospitalization, mean 5.97 days vs. mean 5.98 days Acute: 5.55 days vs.4.08 days (no p value provided) Chronic: 6.27 days vs. 9.29 days Improvement 64% following initial treatment, 88% decreased pain at discharge vs. 64% and 85% For both groups, approximately 50% of patients reported decreased pain at discharge, with 5% asymptomatic. Similar response among acute, subacute, chronic.
Mayer, 2005 Treating acute low back pain with continuous low-level heat wrap therapy and/or exercise: a randomized controlled trial	Patients randomly assigned to: 1) Heat wrap 2) Directional preference-based exercise 3) Heat wrap and exercise combination or 4) Control - booklet Treatment administered immediately for 5 consecutive days and included 4 visits to the study center over 1 week. 1) Wrap reaching temperature of 40 degrees C within 30 minutes, delivering $\geq$ 8 hours of controlled heat. Worn 8 hours/day. 2) Exercise protocol customized for each patient and supervised by a therapist. Standardized full range of motion movements stressing the end range in the directional preference that was displayed at the initial evaluation according to McKenzie concepts. 1 - 2 sets of 15 - 20 repetitions for each exercise at Visits 1, 2 and 3 under supervision, with instruction to perform same exercises at home 1x every hour while awake for 5 consecutive days. 3) Same protocol as 1) and 2) above, except patients wore wrap $\geq$ 1 hour before exercise on visit 1 and were advised to wear the wrap for 4 hours before exercise on visits 2 and 3. 4) Patients given booklet *Acute Low Back Problems in Adults, Patient Guide: Understanding Acute Low Back Problems* . Therapist reviewed booklet with patients and advised then to read it thoroughly at home and to closely follow recommendations, except refrain from specific exercises for low back, use of heat or cold or spinal manipulation. All patients given group-specific home instruction sheets including restrictions on use of other treatments. No restrictions on medication use. Days 2, 4 and 7 - study visits and assessments.	Differential improvement more striking at Day 7 than at earlier points in study. Functional improvement at Day 7: heat + exercise improvement 84%, 95%, and 175% > than heat wrap, exercise, and booklet, respectively ($p<0.05$). 72% of patients returned to pre-injury function vs. 20%, 20% and 19% for heat wrap, exercise and booklet ($p<0.05$). Day 7 improvement heat+exercise vs. control: 72.2% vs. 19.0%, OR 11.05, $p=0.003$. Disability reduction: heat + exercise reduction 93%, 139%, and 400% > vs. heat wrap, exercise and booklet, respectively ($p<0.05$). Day 7 reduction heat+exercise vs. control: 71.4% vs. 44.0%, OR 3.18, $p=0.028$ Pain relief: heat + exercise relief 70% greater vs. exercise and 143% greater vs. booklet ($p<0.05$). Day 7 pain relief heat+exercise vs. control: 95.2% vs. 40.0%, OR 29.85, $p=0.003$.

Appendix E50. Trials of Superficial Heat-Cold Included in the APS/ACP Review

Author, Year, Title	Duration of Followup	Loss to Followup	Compliance to Treatment	Adverse Events and Withdrawals Due To Adverse Events	Quality Rating	Comments
Landen, 1967 Heat or cold for the relief of low back pain?	Treatment duration approximately 4 - 10 days	117/143 (82%) completed	Data not provided. Compliance assumed to be high - hospital setting	Not reported		Very small n No standardized measurements used No statistical analysis
Mayer, 2005 Treating acute low back pain with continuous low-level heat wrap therapy and/or exercise: a randomized controlled trial	Treatment: 5 days followup: 2 days after treatment conclusion	92/100 (92%) completed Drops: wrap: 3 exercise: 1 heat+exercise: 3 booklet: 1	1 drop from heat+exercise due to noncompliance. No other compliance information provided.	No adverse events reported by patients.		Placebo effect not ruled out - exercise+heat patients received 2x attention & intervention as those in other groups

Appendix E50. Trials of Superficial Heat-Cold Included in the APS/ACP Review

Author, Year, Title	Purpose of Study	Study Design	Inclusion Criteria	Exclusion Criteria	Number of Treatment and Control Subjects (number approached, number eligible, number enrolled)
Melzack, 1980 Ice massage and transcutaneous electrical stimulation: comparison of treatment for low-back pain	To examine the relative effectiveness of ice massage and TES for relief of low-back pain	Prospective crossover			Number approached and eligible not reported. 44 subjects total 22: ice massage then TES 22: TES then ice massage 29 of these received a 5th treatment session in which they chose ice massage or TES, depending on what they viewed as most helpful

Appendix E50. Trials of Superficial Heat-Cold Included in the APS/ACP Review

Author, Year, Title	Subject Age, Gender, Diagnosis	Country and Setting	Sponsor	Measures
Melzack, 1980 Ice massage and transcutaneous electrical stimulation: comparison of treatment for low-back pain	21/44 (48%) women history of chronic low back pain with mean duration of 7.4 years	Canada pain center at hospital	Grant from Natural Sciences and Engineering Research Council of Canada	Case history McGill Pain Assessment Questionnaire: measured degree of pain relief with Pain Rating Index (PRI) and Present Pain Intensity (PPI).

Appendix E50. Trials of Superficial Heat-Cold Included in the APS/ACP Review

Author, Year, Title	Type of Intervention	Results
Melzack, 1980 Ice massage and transcutaneous electrical stimulation: comparison of treatment for low-back pain	Patients assigned alternately to: 1) two treatments with ice massage followed by 2 treatments with TES or 2) two TES followed by 2 ice massage treatments. 29/44 received a 5th treatment session in which they chose ice massage or TES, depending on what they viewed as most helpful. Treatment intervals 1 - 2 weeks. TES: EEG disc electrodes placed at midline of lower back at L3 and S1, and at lateral malleolus of the side with the most severe pain. An indifferent electrode placed at back of the knee. Electrodes attached to a Grass S8 stimulator set to produce square wave pulses at 3/sec. Voltage level mildly painful but not unbearable. Stimulation delivered simultaneously to the 3 sites for 30 minutes. Ice massage: At the 3 sites described above, the skin was gently massaged by an ice cube held by a gauze pad. Sites stimulated in succession by applying the massage for a maximum of 7 minutes at each site with a 3 minute rest interval between stimulation periods. Patients asked to report sensations during massage. If pain reported & treatment stop requested, treatment was resumed at the next site after a 3 minute interval. Procedure continued, returning to the 1st site if necessary, until a total of 30 minutes elapsed. When patients returned for the next treatment in the series, they were asked to estimate duration of pain relief after the previous treatment. 30 patients successfully contacted for followup 1 - 12 months (mean 6 months) after completion of the last session.	No treatment order effect. Both ice massage and TES produced reduced pain, with 67% - 69% obtaining relief > than 33% with either method. No significant treatment difference between groups in independent samples. In crossover analysis, mean percent decrease in PRI scores are comparable for both treatments, and PPI decrease is greater after ice massage than TES ($p<0.02$ in 2-tailed t, N=38). Further analysis showed that ice massage and TES are equally effective for high and low levels of initial pain. Of the 29 patients asked to chose their preferred treatment for a 5th session, 13 (45%) chose TES, 9 (31%) chose ice, and 5 (17%) viewed neither treatment as effective and requested another therapy. followup: In response to questions 1 - 12 months after treatment completion, 14/30 (47%) reported continued treatment, 7/30 (23%) had purchased/rented TES devices and used them daily or when needed, 5/30 (17%) continued to practice ice massage administered by a family member or friend, 2/30 (7%) reported wanting ice massage and unable to obtain it, and 2/30 (7%) described pain relief with no therapy needed or use of other forms of therapy

Appendix E50. Trials of Superficial Heat-Cold Included in the APS/ACP Review

Author, Year, Title	Duration of Followup	Loss to Followup	Compliance to Treatment	Adverse Events and Withdrawals Due To Adverse Events	Quality Rating	Comments
Melzack, 1980 Ice massage and transcutaneous electrical stimulation: comparison of treatment for low-back pain	1 - 12 months, mean of 6 months	30/44 (68%) available for followup questions	not reported	not reported		Wide range for followup: 1 - 12 months Small N Unclear why only 29/44 were offered 5th treatment session

Appendix E50. Trials of Superficial Heat-Cold Included in the APS/ACP Review

Author, Year, Title	Purpose of Study	Study Design	Inclusion Criteria	Exclusion Criteria	Number of Treatment and Control Subjects (number approached, number eligible, number enrolled)
Nadler, 2002 Continuous low-level heat wrap therapy provides more efficacy than ibuprofen and acetaminophen for acute low back pain	To compare the efficacy of continuous low-level heat wrap therapy (40C, 8 hours/day) with that of ibuprofen (1200 mg/day) and acetaminophen (4000 mg/day) in subjects with acute nonspecific low back pain	Prospective, randomized, single-blind (investigator) comparative trial.			Number approached and eligible not reported. 371 randomly assigned: 113 to heat wrap 113 to acetaminophen 106 to ibuprofen 20 to oral placebo 19 to unheated back wrap

Appendix E50. Trials of Superficial Heat-Cold Included in the APS/ACP Review

Author, Year, Title	Subject Age, Gender, Diagnosis	Country and Setting	Sponsor	Measures
Nadler, 2002 Continuous low-level heat wrap therapy provides more efficacy than ibuprofen and acetaminophen for acute low back pain	216/371 (58%) women, mean age 35.94 (SD 10.59). Acute, nonspecific low back pain of at least moderate intensity ($\geq$ 2 on 6 point scale)	USA 11 sites	Proctor and Gamble. 6 authors are employees of Proctor & Gamble Health Sciences Institute. Lead author is a paid consultant.	Pain relief: measured by 6-point verbal rating scale Roland-Morris Disability Questionnaire: assessed disability lateral trunk flexibility: derived score from within-subject mean measure of trunk flexion for the left and right sides. muscle stiffness: measured by 101-point numerical rating scale. At first visit, medical history and physical exam, including neurological and skin assessments. Patients given questionnaires and diaries to complete. On day 4, lateral trunk flexibility, disability, and skin quality assessed.

Appendix E50. Trials of Superficial Heat-Cold Included in the APS/ACP Review

Author, Year, Title	Type of Intervention	Results
Nadler, 2002 Continuous low-level heat wrap therapy provides more efficacy than ibuprofen and acetaminophen for acute low back pain		Pain relief: mean Day 1 score for heat wrap (2) higher than acetaminophen (1.32) p=0.0001 or ibuprofen (1.51) p=0.0007. Differences observed at individual hourly time points comprising the primary end point. Day 2 mean pain relief scores greater than acetaminophen (2) p=0.0001 or ibuprofen (2.06) p=0.0001. Scores for Days 3 - 4 higher for heat wrap (2.61) vs. acetaminophen (1.95) p=0.0009 or ibuprofen (1.68) p=0.0001. Muscle stiffness: reduction in Day1 mean muscle stiffness score greater with heat wrap (16.3) vs. acetaminophen (10.5) p=0.001 or ibuprofen(13.3) 0=0.10. At individual time points from hours 4 through 8 on Day 1, heat wrap had decreased muscle stiffness scores (p<0.05). Day 1 and Day 2 data combined: > decrease in mean muscle stiffness scores for heat wrap (26.6) vs. acetaminophen (19.7) p=0.006 or ibuprofen (17.6) p=0.009. Scores on Days 3 to 4 were decreased more for heat wrap (mean 26.6) vs. acetaminophen (17.1) p=0.001) or ibuprofen (14.8) p=0.0001. Lateral trunk flexibility: After 2 days of treatment, change in flexibility greater for heat wrap (mean 4.28 cm) vs. acetaminophen (2.93 cm) p=0.009 or ibuprofen (2.51cm) p=0.001. Day 4 findings similar. Roland-Morris disability assessment: On Day 2, reduction in score for heat wrap (mean 3.9) was directionally greater than for acetaminophen (3) p=0.08, and greater than for ibuprofen (2.6) p=0.009. By Day 4, reduction in disability score for the heat wrap (4.9) was greater vs. acetaminophen (2.9) p=0.0007 or ibuprofen (2.7), p=0.0001. See AE column

Appendix E50. Trials of Superficial Heat-Cold Included in the APS/ACP Review

Author, Year, Title	Duration of Followup	Loss to Followup	Compliance to Treatment	Adverse Events and Withdrawals Due To Adverse Events	Quality Rating	Comments
Nadler, 2002 Continuous low-level heat wrap therapy provides more efficacy than ibuprofen and acetaminophen for acute low back pain	Treatment: 2 consecutive days followup: 2 days after treatment completion	363/371 (98%) completed heat wrap: 111/113 acetaminophen: 111/113 ibuprofen: 102/106 placebo: 19/20 unheated wrap: 20/19	5 participants did not comply: heat wrap: 1 voluntary withdrawal acetaminophen: 2 protocol violations ibuprofen: 1 voluntary withdrawal, 1 drop due to AE	Systemic AEs more common in ibuprofen group (10.4%) than heat wrap (6.2%) or acetaminophen (4.4%). Nausea was the most frequently reported AE for all groups. Only 1 participant dropped out of the study because of an AE - an upper respiratory infection in the ibuprofen group. 1 participant in the heat wrap group experienced minor redness in the area of wrap application on Day 2. This resolved spontaneously 1 hour after wrap removal.		

Appendix E50. Trials of Superficial Heat-Cold Included in the APS/ACP Review

Author, Year, Title	Purpose of Study	Study Design	Inclusion Criteria	Exclusion Criteria	Number of Treatment and Control Subjects (number approached, number eligible, number enrolled)
Nadler, 2003a Continuous low-level heat wrap therapy for treating acute nonspecific low back pain	To evaluate the efficacy of 8 hours of continuous low-level heat wrap therapy for the treatment of acute nonspecific low back pain.	Prospective, randomized, parallel, single-blind (investigator) placebo-controlled, multicenter clinical trial.			Number approached and eligible not reported. 219 in final study population, evaluation of efficacy (heat wrap n=95; oral placebo n=96) blinding (oral ibuprofen n=12; unheated back wrap n=16).

Appendix E50. Trials of Superficial Heat-Cold Included in the APS/ACP Review

Nadler, 2003b Overnight use of continuous low-level heat wrap therapy for relief of low back pain	To compare efficacy and safety of 8 hours of continuous, low-level heat wrap therapy administered during sleep.	Prospective, randomized, single-blind (investigator), placebo-controlled, multicenter clinical trial	Age 18 to 55 with acute, nonspecific LBP, pain intensity moderate or higher. Ambulatory, traumatic origin, agreement to abstain from therapeutic interventions that could influence efficacy or safety	Regular insomnia for > 1 week or inability to remain sleeping at least 6 hours. Radiculopathy or other neurological deficits of lower extremities. History of back surgery, diabetes, poor circulation and others.	Number approached and eligible not reported. 76 total randomized 33 heat wrap 34 oral placebo 5 unheated heat wrap 4 oral ibuprofen

Appendix E50. Trials of Superficial Heat-Cold Included in the APS/ACP Review

Author, Year, Title	Subject Age, Gender, Diagnosis	Country and Setting	Sponsor	Measures
Nadler, 2003a Continuous low-level heat wrap therapy for treating acute nonspecific low back pain	119/219 (54.3%) women, mean age 36.05 (SD 11.17) Acute nonspecific low back pain intensity moderate or higher.	USA 5 community-based research facilities: Huntington and Great Neck, NY; Bryan and Dallas, TX; and Columbus, OH	Proctor and Gamble. Lead author is paid consultant to Proctor and Gamble. 4 authors are employees of Proctor & Gamble Health Sciences Institute.	Pretreatment baseline: muscle stiffness, lateral trunk flexibility, disability assessment (Roland-Morris Disability Questionnaire [RMDQ]). Treatment efficacy: pain relief (6 point rating scale) muscle stiffness: 101 point numeric rating scale lateral trunk flexibility: derived score calculated as within-subject mean measure of trunk flexion for the left and right sides. Measured at each study visit. disability: measured study days 3 and 5 Medical history and physical examination (including neurological and back skin assessments) at visit 1. Skin assessment also at visit 5. Patient diaries for recording pain relief and muscle stiffness

Appendix E50. Trials of Superficial Heat-Cold Included in the APS/ACP Review

Nadler, 2003b Overnight use of continuous low-level heat wrap therapy for relief of low back pain	Acute, nonspecific low back pain	USA 2 community-based research facilities	Proctor and Gamble. 4 authors employees of P & G - lead author is paid consultant.	Baseline muscle stiffness, lateral trunk flexibility, disability assessment, skin quality. Pain relief: 6-point VAS and diary Muscle stiffness: 101-point numeric rating scale (NRS) and diary Pain affect: 101-point NRS and diary LBP disability assessed with Roland-Morris Disability Questionnaire Lateral trunk flexibility and disability Skin quality: 4-point scale Sleep quality and onset of sleep difficulty: 6-point VRS and diary Time out of bed at night: diary

Appendix E50. Trials of Superficial Heat-Cold Included in the APS/ACP Review

Author, Year, Title	Type of Intervention	Results
Nadler, 2003a Continuous low-level heat wrap therapy for treating acute nonspecific low back pain	Subjects stratified by baseline pain intensity and gender and randomized to one of the following groups: 1) wearable heat wrap (ThermaCare Heat wrap) which heats to 104 degrees F within 30 minutes of exposure to air and maintains this temperature continuously for > 8 hours of wear 2) oral placebo (2 tablets, 3 times daily, spaced 6 hours apart) 3) oral analgesic (ibuprofen 200 mg, 2 tablets, 3 times daily, spaced 6 hours apart 4) unheated wrap in a randomized ratio of 6:6:1:1. evaluation of efficacy (heat wrap n=95; oral placebo n=96) blinding (oral ibuprofen n=12; unheated back wrap n=16). All treatments administered for 3 consecutive days with 2 days of followup. Back wraps were worn for approximately 8 hours daily for 3 consecutive days.	On day 1, heat wrap group > pain relief (1.76 + .10 vs 1.05 + .11, p<0.001). Mean pain relief scores for heat wrap were higher than placebo for 16/20 individual time points evaluated (p<0.05). Incidence of complete pain relief days 1 through 5 higher for heat wrap (15.4% incidence) vs placebo (6.6% incidence) p=0.04; odds ratio 2.89. Days 4 and 5 pain relief scores higher for heat wrap (mean 2.50 + .16) vs placebo (mean 1.56 + .18), p<0.0001. Day 1 mean muscle stiffness lower for heat wrap (43.1 + 1.21) vs placebo (47.6 + 1.21), p=0.008. Muscle stiffness scores lower for heat wrap vs placebo for 15/20 individual time points evaluated (p<.05). Days 4 and 5 mean muscle stiffness score for heat wrap (mean 32.2 + 1.99) lower vs placebo (43.1 + 2.03) p<0.0002. Lateral flexibility for heat wrap was higher vs placebo at all time points (p<.01), and persisted through followup (18.6 + .44 cm vs 16.5 + .45 cm) p=0.001. Day 3 mean disability scores for heat wrap (mean 5.3) were lower vs placebo (mean 7.4) p<0.0002. Day 5 mean disability scores for heat wrap (mean 4.6) were lower vs placebo (mean 6.7), p<0.001.

Appendix E50. Trials of Superficial Heat-Cold Included in the APS/ACP Review

Nadler, 2003b Overnight use of continuous low-level heat wrap therapy for relief of low back pain	Stratification by baseline pain intensity and gender, then randomized in 6:6:1:1 ratio to: A. Heat wrap - heats to 104 degrees within 30 minutes and maintains for 8 hours B. Oral placebo - 2 tablets C. Oral ibuprofen (2 tablets, 400 mg total) D. Unheated wrap Wraps applied 15-20 minutes before bedtime and worn during sleep for approximately 8 hours, 3 consecutive nights. Oral treatments given 15-20 minutes before bedtime for 3 consecutive nights.	Heat wrap vs. placebo Pain relief higher at 20 time points from day 2 through 5 ($p \leq 0.003$ for each point) Mean pain relief score day 2 through day 4 after 3 nights treatment: 2.75 vs.1.45, p=0.00005. Day 2, hours 0 through 8: 2.36 vs. 1.28, p<0.001 Mean daytime pain relief score days 2 though 4, 8 hours after waking: 2.69 vs. 1.46, p=0.00005. Mean pain relief score days 4 and 5: 2.90 vs. 1.60, p=0.0001. Decreased morning muscle stiffness: day 4 mean score 32.5 vs. 46.9, p<0.001 Increased lateral flexibility: mean score baseline to day 4: 20.0 vs. 17.0, p<0.002 Decreased low back disability, mean score (RMDQ) baseline to day 4: 3.6 vs. 5.8, p=0.005 Mean quality of sleep score days 2 through 4: 2.81 vs. 2.42, p<0.01

Appendix E50. Trials of Superficial Heat-Cold Included in the APS/ACP Review

Author, Year, Title	Duration of Followup	Loss to Followup	Compliance to Treatment	Adverse Events and Withdrawals Due To Adverse Events	Quality Rating	Comments
Nadler, 2003a Continuous low-level heat wrap therapy for treating acute nonspecific low back pain	Treatment: 3 consecutive days followup: 2 days after treatment completion	13/219 (5.9%) excluded from evaluable data set for primary analysis	8 dropped due to protocol violations, 2 due to voluntary withdrawal without adverse events	Heat wrap: 1/95 subjects experienced skin redness by study day 5, which resolved without treatment. I subject in oral placebo withdrew due to hip pain from a fall on the ice. No other AEs reported.		

Appendix E50. Trials of Superficial Heat-Cold Included in the APS/ACP Review

Nadler, 2003b Overnight use of continuous low-level heat wrap therapy for relief of low back pain	Treatment: 3 consecutive nights followup: 2 days after treatment completion	70/76 (92%) completed heat wrap: 31/33 oral placebo: 32/33 oral ibuprofen: 4/4 unheated wrap: 3/5	1 drop (heat wrap) due to noncompliance. 4 drops (1 heat wrap, 1 oral placebo, 2 unheated wrap) due to protocol violation	No serious adverse events. 2 from placebo withdrew due to nausea, vomiting. Number of heat wrap AEs similar to placebo. Systemic AEs: > frequent in ibuprofen group (25%) vs. primary treatment. Most common AEs: heat wrap - application site reaction (15%), faint skin pinkness (15%), with 1 subject progressing to moderate arrhythmia; placebo - headache (12%); ibuprofen - abdominal pain (25%). All application site reactions resolved without treatment in 1-2 days.		Oral ibuprofen and unheated wrap groups very small

Appendix E50. Trials of Superficial Heat-Cold Included in the APS/ACP Review

Author, Year, Title	Purpose of Study	Study Design	Inclusion Criteria	Exclusion Criteria	Number of Treatment and Control Subjects (number approached, number eligible, number enrolled)
Nuhr, 2004 Active warming during emergency transport relieves acute low back pain	To evaluate effects of external active warming on acute back pain during rescue transport to hospital.	Prospective randomized blinded trial in a prehospital emergency system			Number approached and eligible not reported. 108 screened 100 randomized, 50 to Group 1 and 50 to Group 2.

Appendix E50. Trials of Superficial Heat-Cold Included in the APS/ACP Review

Author, Year, Title	Subject Age, Gender, Diagnosis	Country and Setting	Sponsor	Measures
Nuhr, 2004 Active warming during emergency transport relieves acute low back pain	Mean age: 45 66% women Acute lower back pain > 60 mm on visual analogue scale, duration < 6 hours before arrival of emergency team.	Austria Prehospital emergency system	Vienna Red Cross	Morphometric characteristics (temperature, oscillometric blood pressure, heart rate) measured immediately after entering ambulance and on arrival at destination hospital. Patient self-rating of pain and anxiety level using visual analog scales (0-100 mm).

Appendix E50. Trials of Superficial Heat-Cold Included in the APS/ACP Review

Author, Year, Title	Type of Intervention	Results
Nuhr, 2004 Active warming during emergency transport relieves acute low back pain	Random assignment to 2 groups: 1) active warming with a carbon-filter electric heating blanket during transfer to hospital 2) passive warming with a woolen blanket during transfer to hospital Patients in both groups were covered first with the electric and then the wool blanket. The heating system on the electric blanket was activated at the emergency site for those assigned to Group 1	Pain scores at hospital arrival differed significantly between Groups 1 and 2 ($p<0.01$). Group 1 pain was reduced from 74.2 ± 8.5 mm VAS to 41.9 ± 18.9 VAS ($p<0.01$) vs. 73.3 ± 11.9 mm VAS and 74.1 ± 12.0 mm VAS in Group 2. Anxiety scores at hospital arrival differed from Group 1 (59.0 ± 14.0 mm VAS) vs. Group 2 (93.5 ± 18.4 mm VAS), $p<0.01$. Number of vasoconstricted patients arriving at the hospital greater in Group 2 (39/4 constricted/dilated) vs. Group 1 (1/46 constricted/dilated), $p<0.01$. Heart rate drop at hospital arrival greater in Group 1 vs. Group 2 , $p<0.01$. After diagnosis, 3 patients from Group 1 and 7 from Group 2 were excluded because of pain due to disorders other than spinal or muscular. Data from 47/50 (94%) in Group 1 and 43/50 (86%) in Group 2 were analyzed.

Appendix E50. Trials of Superficial Heat-Cold Included in the APS/ACP Review

Author, Year, Title	Duration of Followup	Loss to Followup	Compliance to Treatment	Adverse Events and Withdrawals Due To Adverse Events	Quality Rating	Comments
Nuhr, 2004 Active warming during emergency transport relieves acute low back pain	Treatment period only: mean 25.5 minutes	After diagnosis, 3 patients from Group 1 and 7 from Group 2 were excluded because of pain due to disorders other than spinal or muscular. Data from 47/50 (94%) in Group 1 and 43/50 (86%) in Group 2 were analyzed.	n/a: full compliance implied	Not reported		

Please see Appendix C. Included Studies for full study references.

Appendix E51. Data Abstraction of Systematic Reviews of Heat-Cold

Author, Year	Comparison	Data Sources	Number and Type of Studies	Interventions and Number of Patients	Methods for Rating Methodological Quality of Primary Studies	Methods for Synthesizing Results of Primary Studies
Studies included in the APS review						
French 2005	Heat vs. no heat Cold vs. no cold Heat vs. cold Heat vs. other active treatments Cold vs. other active treatments Heat + another treatment vs. other treatment alone	MEDLINE, EMBASE, CCCRCT through October 2005	9 studies: 5 RCTs, 1 CCT, 3 crossover studies Acute pain (1 trial), mixed acute and subacute pain (4 trials), chronic pain (3 trials), mixed acute, subacute and chronic pain (1 trial) Heat vs. placebo (4 trials), heat vs. cold (2 trials), heat vs. other interventions (4 trials), cold vs. other interventions (1 trial) (some trials evaluated multiple comparisons)	A. Heat (hot pack or heated wrap; n=446) B. Cold (cold pack or ice massage; n=94) C. Other active interventions (NSAID, n=238; exercise, n=25; lumbar support, n=38; heat + other intervention, n=24) D. No heat/cold (n=216)	Cochrane Back Group criteria (2003)	Qualitative analysis judging level of evidence (strong, moderate, limited conflicting or no evidence) due to limited poolable data

Appendix E51. Data Abstraction of Systematic Reviews of Heat-Cold

Author, Year	Results	Adverse Events	Quality
Studies included in the APS review			
French 2005	A vs. B No qualitative analysis; evidence from one CCT and one crossover study (both low quality). The CCT found no difference between hot packs and ice massage in a mixed population (treatment duration and followup not reported) and the crossover study found ice massage superior to hot packs in a chronic pain population after 2 20-minute treatments with each. A vs. C (specified below) Acute or subacute population Pain, VAS mean difference day 1 or 2, heat vs. (1 trial each): acetaminophen 0.90 (95% CI 0.50 to 1.30); ibuprofen 0.65 (95% CI 0.25 to 1.05); exercise 0.40 (95% CI -0.15 to 0.95) *higher score favors heat Pain, VAS mean difference day 4, heat vs. (1 trial each): acetaminophen 0.74 (95% CI 0.31 to 1.17); ibuprofen 1.05 (95% CI 0.62 to 1.48); exercise 0.30 (95% CI -0.41 to 1.01) *higher score favors heat Pain, VAS mean difference day 7, heat vs. (1 trial): exercise 0.30 (95% CI -0.68 to 1.28) *higher score favors heat Function, RMDQ mean difference, day 4, heat vs. (1 trial each): acetaminophen 2.00 (95% CI 0.86 to 3.14); ibuprofen 2.20 (95% CI 1.11 to 3.29) *higher score favors heat Function, RMDQ mean difference, day 2, heat vs. (1 trial): exercise -0.70 (95% CI -2.09 to 0.69)*lower score favors heat Function, RMDQ mean difference, day 4, heat vs. (1 trial): exercise -0.90 (95% CI -2.84 to 1.04)*lower score favors heat Function, RMDQ mean difference, day 7, heat vs. (1 trial): exercise -0.50 (95% CI -2.72 to 1.72)*lower score favors heat		Good

Appendix E51. Data Abstraction of Systematic Reviews of Heat-Cold

Author, Year	Results	Adverse Events	Quality
French 2005 (cont.)	(A + C) vs. C alone Acute or subacute population Pain, VAS mean difference, heat + exercise vs. exercise, day 2 (1 trial): 0.50 (95% CI -0.21 to 1.21) *higher score favors heat + exercise Pain, VAS mean difference, heat + exercise vs. exercise, day 4 (1 trial): 0.80 (95% CI -0.03 to 1.63) *higher score favors heat + exercise Pain, VAS mean difference, heat + exercise vs. exercise, day 7 (1 trial): 1.40 (95% CI 0.69 to 2.11) *higher score favors heat + exercise Function, RMDQ mean difference, heat + exercise vs. exercise, day 2 (1 trial): 0.60 (95% CI -0.79 to 1.99) *lower score favors heat + exercise Function, RMDQ mean difference, heat + exercise vs. exercise, day 4 (1 trial): -1.20 (95% CI -3.14 to 0.74) *lower score favors heat + exercise Function, RMDQ mean difference, heat + exercise vs. exercise, day 7 (1 trial): -3.20 (95% CI -5.42 to -0.98) *lower score favors heat + exercise (A + C) vs. A alone Pain, VAS mean difference, heat + exercise vs. heat, day 2 (1 trial): 0.10 (95% CI -0.61 to 0.81) *higher score favors heat + exercise Pain, VAS mean difference, heat + exercise vs. heat, day 4 (1 trial): 0.50 (95% CI -0.21 to 1.21) *higher score favors heat + exercise Pain, VAS mean difference, heat + exercise vs. heat, day 7 (1 trial): 1.10 (95% CI 0.22 to 1.98) *higher score favors heat + exercise Function, RMDQ mean difference, heat + exercise vs. heat, day 2 (1 trial): 1.30 (95% CI -0.07 to 2.67) *lower score favors heat + exercise Function, RMDQ mean difference, heat + exercise vs. heat, day 4 (1 trial): -0.30 (95% CI -2.24 to 1.64) *lower score favors heat + exercise Function, RMDQ mean difference, heat + exercise vs. heat,, day 7 (1 trial): -2.70 (95% CI -4.92 to -0.48) *lower score favors heat + exercise		

Appendix E51. Data Abstraction of Systematic Reviews of Heat-Cold

Author, Year	Results	Adverse Events	Quality
French 2005 (cont.)	A vs. D Acute or subacute population Pain, VAS mean difference up to day 5 (2 trials): 1.06 (95% CI 0.68 to 1.45) *higher score favors heat Function, RMDQ mean difference day 4 (2 trials): -2.12 (95% CI -3.07 to -1.18) *lower score favors heat B vs. C One trial of ice massage vs. TENS; included in TENS section of the report (found no difference between ice massage and TENS) B vs. D No evidence	A vs. D Skin flushing at application site (2 trials): 5% (6/128) vs. 0.8% (1/130); RR 6.09 (95% CI 0.74 to 50) All other comparisons: not reported	

Please see Appendix C. Included Studies for full study references.

Appendix E52. Data Abstraction of Randomized Controlled Trials of Heat-Cold

Author, Year	Country Number of Centers and Setting	Inclusion Criteria	Number Randomized, Analyzed Attrition	Intervention	Study Participants	Duration of Pain (acute, subacute, chronic)
Kettenmann 2007	Germany Single-center	Ambulatory orthopedic surgery patients age 18 to 80 years with acute low back pain VAS score >0 to <5 (scale 0-10) Excluded: chronic pain, RA, postsurgical pain, CV disorder, chronic skin condition, diabetes, pregnancy	Randomized: 38 Analyzed: 30 Attrition: 21% (8/38)	A. Continuous low-level heat wrap (ThermaCare®) 4 hours/day for 4 days (n=15) B. No heat wrap (oral NSAIDs allowed as needed but there was no formal protocol for their use) (n=15)	A vs. B Mean age 56 vs. 58 years 53% vs. 80% female Race not reported Mean pain (VAS) 4.1 vs. 3.9	Acute Mean not reported; duration >3 months excluded

Appendix E52. Data Abstraction of Randomized Controlled Trials of Heat-Cold

Author, Year	Duration of Followup	Results (list results for acute, subacute and chronic separately)	Adverse Events Including Withdrawals	Funding Source	Quality	Comments
Kettenmann 2007	5 days (4 treatment days + 1 day post-treatment)	A vs. B Pain, patient assessed severity (no pain to very severe pain, VAS scale 0-100) day 1: 40 vs. 52; p=NS; day 2: 30 vs. 44; p=NS; day 3: 31 vs. 57; p=0.02; day 4: 27 vs. 47; p=0.04 (pain values presented graphically) Function, proportion of patients woken from sleep due to pain: significantly lower proportion with heat wrap use at days 2 (p=0.16), 3 (p=0.002) and 4 (p=0.001)	Not reported	Proctor & Gamble	Fair	

Please see Appendix C. Included Studies for full study references.

Appendix E53. Trials of Low-Level Lasers Included in the APS/ACP Review

Author, Year, Title	Purpose of Study	Study Design	Inclusion Criteria	Exclusion Criteria	Number of Treatment and Control Subjects (number approached, number eligible, number enrolled)
Monticone, 2004 Symptomatic efficacy of stabilizing treatment versus laser therapy for sub-acute low back pain with positive tests for sacroiliac dysfunction: a randomized clinical controlled trial with 1 year follow-up	To compare the efficacy of stabilizing treatment (orthesis and exercise, with previous mesotherapy) directly targeted to sacroiliac dysfunction vs. He-Ne laser therapy in patients with sub-acute or low back pain and positive sacroiliac signs.	RCT	LBP for 7 days to 3 months in one sacroiliac region, with positive Laslett's pain-provocation and Mens's stability tests	Spinal or pelvic co-morbidity on CT or MRI or cognitive deficiencies	449 approached, number eligible not reported 22 enrolled, 11 to laser and 11 to group stabilization
Gur, 2003 Efficacy of low power laser therapy and exercise on pain and functions in chronic low back pain	To compare efficacy of low power laser (LPL) therapy (Gallium-Arsenide), exercise, and LPL with exercise for chronic low back pain.	RCT	Chronic low back pain for at least 1 year, age 20-50 years	Not pregnant, no previous spinal surgery, no neurological deficits, abnormal laboratory findings, or systemic and psychiatric illnesses	Number approached and eligible not reported 75 randomized, 25 to laser + exercise, 25 to laser only, and 25 exercise only

Appendix E53. Trials of Low-Level Lasers Included in the APS/ACP Review

Author, Year, Title	Subject Age, Gender, Diagnosis	Country and Setting	Sponsor	Measures
Monticone, 2004 Symptomatic efficacy of stabilizing treatment versus laser therapy for sub-acute low back pain with positive tests for sacroiliac dysfunction: a randomized clinical controlled trial with 1 year follow-up	Mean age: 44 years Female gender: 45% Baseline pain: Not reported Duration of pain: 7 days to 3 months per protocol	Italy	Not reported	Assessed pretreatment, end of treatment, and 12 months post-treatment VAS: to assess pain at rest, during movement, following axial pressure on the sacroiliac joint After treatment and 12 month follow-up: Laslett's pain provocation tests, Mens's stability tests
Gur, 2003 Efficacy of low power laser therapy and exercise on pain and functions in chronic low back pain	Mean age 35.6 Female gender: 69.3% Race: Not reported Mean duration of low back pain: 24.8 months	Turkey university rehab center	Not reported	VAS: to evaluate pain at beginning and end of treatment. Roland Disability Questionnaire (RDQ): to evaluate function Modified Oswestry Disability Questionnaire (MODQ): to evaluate function Schlober test, flexion and lateral flexion: to evaluate lumbar range of motion at pre- and post-treatment

Appendix E53. Trials of Low-Level Lasers Included in the APS/ACP Review

Author, Year, Title	Type of Intervention	Results
Monticone, 2004 Symptomatic efficacy of stabilizing treatment versus laser therapy for sub-acute low back pain with positive tests for sacroiliac dysfunction: a randomized clinical controlled trial with 1 year follow-up	A: He-Ne laser therapy targeting the sacroiliac region. 10 daily sessions Mon - Fri, for a total of 2 weeks.mesotherapy, dynamic sacroiliac support (ILSA) and exercise. B: Stabilization: mesotherapy 2x/week for 8 total sessions. NSAIDs administered in-site using Luer needles, 27G and 0.4x4 mm. Sacroiliac girdle: daily orthosis for 4 weeks. Dynamic support with special sacroiliac girdle (ILSA). Exercise and education: At the end of orthotic treatment, 2 sessions to learn pelvic stabilization exercises and to receive postural education. Daily exercise through follow-up recommended	Laser vs. stabilization, mean change from baseline at end of treatment and 12 months following end of treatment Pain at rest (VAS 0 to 10): 0 vs. -5, -1 vs. -6 Pain with movement (VAS 0 to 10): -4 vs. -7; -2 vs. -8
Gur, 2003 Efficacy of low power laser therapy and exercise on pain and functions in chronic low back pain	A: Laser only: Treatment sessions 5 x/week for 4 weeks. External laser over a series of standardized fields designed to include L-4 to L-5 and L-5 to S1 apophyseal capsules, dorsolumbar fascia, and interspinous ligaments, as well as gluteal fascia, posterior sacroiliac ligaments, hamstrings, and gastro-soleus muscles of which pain points were palpitated from the low back to the foot. 4 minute stimulation for each point. 1 J/cm2 (10.1 cm2 energy density, 2.1 kHz pulse frequency, 10W diode power, 4.2 mW average power, 1 cm2 surface) at each point. Approximately 30 minute stimulation time to cover entire area. Treatment administered by 2 physical therapists using standard technique. Gallium-arsenide laser (class IIIb Laser Product). B: Exercise only: 2 sessions/day, 40 sessions total over 4 weeks. 1st session conducted with a physiotherapist, then exercises continued at home by patient. Lumbar flexion and extension, knee flexion, hip adduction exercises, and strength exercises of extremity muscle groups. C: Exercise + laser: All components of laser and exercise described above.	Laser vs. exercise vs. laser + exercise, mean change from baseline Pain (0-10 VAS): -4.2 vs -3.6 vs. -4.4 (NS) Rolad disability questionnaire: -9.7 vs. -9.6 vs. -11.5 (NS) Modified Oswestry disability questionnaire: -16.4 vs. -16.9 vs. -17.6 (NS)

Appendix E53. Trials of Low-Level Lasers Included in the APS/ACP Review

Author, Year, Title	Duration of Followup	Loss to Followup	Compliance to Treatment	Adverse Events and Withdrawals Due To Adverse Events	Comments
Monticone, 2004 Symptomatic efficacy of stabilizing treatment versus laser therapy for sub-acute low back pain with positive tests for sacroiliac dysfunction: a randomized clinical controlled trial with 1 year follow-up	up to 12 month post-treatment	None	Not reported	Not reported	Methods and results difficult to understand due to writing style. Selected group with positive pain provocation tests
Gur, 2003 Efficacy of low power laser therapy and exercise on pain and functions in chronic low back pain	post-therapy measures after 1 month of treatment	No loss to follow-up	Not reported	Not reported	Compliance not reported, which may be especially critical for at-home exercise treatment.

Appendix E53. Trials of Low-Level Lasers Included in the APS/ACP Review

Author, Year, Title	Purpose of Study	Study Design	Inclusion Criteria	Exclusion Criteria	Number of Treatment and Control Subjects (number approached, number eligible, number enrolled)
Basford, 1999 Laser therapy: a randomized, controlled trial of the effects of low-intensity Nd:YAG laser irradiation on musculoskeletal back pain	To assess the effectiveness of low-intensity laser therapy in the treatment of musculoskeletal back pain.	RCT	Age 18-70 years with nonradiating low back pain of more than 30 days duration, women postmenopausal or using effective birth control	Pregnancy, subjects engaged in litigation or workman's compensation issues, surgery, steroids within 30 days	Number approached and eligible not reported 63 enrolled 61 randomized 59 evaluated; 30 randomized to laser and 29 to control
Soriano, 1998 Gallium arsenide laser treatment of chronic low back pain: a prospective, randomized and double blind study	To assess the effectiveness of GaAs laser treatment in patients over age 60 with chronic low back pain	RCT	More than 60 years old, low back pain for more than 3 months	Suspected cancer, osteomyelitis, gout, Page'ts disease or collagen disease, neurologic symptoms or signs of lower limbs, corticosteroid within 30 days	Number approached and eligible not reported 85 enrolled; 43 randomized to treatment and 42 to control

Appendix E53. Trials of Low-Level Lasers Included in the APS/ACP Review

Author, Year, Title	Subject Age, Gender, Diagnosis	Country and Setting	Sponsor	Measures
Basford, 1999 Laser therapy: a randomized, controlled trial of the effects of low-intensity Nd:YAG laser irradiation on musculoskeletal back pain	Mean age: 48 years Female gender: 40% vs. 55% Race: Not reported Duration of symptoms: 6.9 vs. 12.8 months Analgesic use (number/day): 4.6 vs. 4.4	USA physical medicine and rehabilitation clinic	LaserBiotherapy, Inc, Dallas, TX	Oswestry Disability Questionnaire: validated instrument that assessed level of function Modified Schober test to assess lumbar mobility VAS: 100 mm = incredibly severe pain, 0mm = no pain Standard physical examination and history Subjects evaluated before 1st treatment, at session 6, at end of treatment (session 12), and at follow-up, 28 - 35 days after last treatment. Evaluations performed by experienced physician and therapist blinded to and not involved in treatment. Subjects asked about changes in medication use, activity level, perception of benefit, pain nature, and whether they had adverse effects from treatment.
Soriano, 1998 Gallium arsenide laser treatment of chronic low back pain: a prospective, randomized and double blind study	Mean age 63.8 Female gender: 54.7% Race: Not reported Baseline pain: 7.9 vs. 8.1 (1 to 10 scale)	Argentina setting not reported	Not reported	VAS: to evaluate pain at beginning and end of treatment. % pain relief: calculated from VAS. 0-29% relief = poor, 30-59% relief= regular, 60-89% relief= good, 90-100% relief= excellent.

Appendix E53. Trials of Low-Level Lasers Included in the APS/ACP Review

Author, Year, Title	Type of Intervention	Results
Basford, 1999 Laser therapy: a randomized, controlled trial of the effects of low-intensity Nd:YAG laser irradiation on musculoskeletal back pain	A: Laser irradiation for 90 seconds at 8 symmetric points along the lumbosacral spine 3x/week for 4 weeks by therapist blinded to treatment. Probes of the 1.06 um neodymium:yttrium-aluminum-garnet laser emitted 542mW/cm2 for the treated subjects and were inactive for the control subjects. Power readings stable and within 6% of nominal power required except for the last 4 subjects (2 in each group) in whom the output of one probe decreased 40% from nominal level B: Placebo (inactive probes)	Laser vs. placebo, mean change from baseline at end of treatment and 1 month after treatment Oswestry score : -7.7 vs. -2.4; -6.3 vs. -2.1 Maximal pain in the last 24 hours (0-100 VAS): -18.1 vs. -4.6; -16.1 vs. -2.3 Pain with bending (scale not specified): -1.5 vs. -0.6; -1.5 vs. -0.4 Pain with extension (scale not specified): -1.0 vs. 0.0; -1.0 vs. +0.5 Maximal tenderness on palpation (0-100 VAS): -5.6 vs. -1.4; -5.7 vs. -5.2
Soriano, 1998 Gallium arsenide laser treatment of chronic low back pain: a prospective, randomized and double blind study	A: Laser irradiation with a pulsed GaAs diode laser, wavelength 904 nm, pulse frequency 10,000 Hz and pulse width of 200 nsec, peak power of 20 W, average power 40 m W, spot size 150 um2 in area and an angle of divergence of 6 degrees. Laser applied in point contact irradiation technique with a dose of approximately 4 J/cm2 per point. Painful area irradiated using 2 cm grid system. 5 sessions/week x 2 weeks. B: Sham irradiation with a deactivated laser system.	Laser vs. placebo Pain relief >60% at end of treatment: 71% (27/38) vs. 36% (12/33) ($p<0.007$). Complete pain resolution at end of treatment: 45% (17/38) vs. 15% (5/33) ($p<0.01$) Proportion of patients with good or excellent response at end of treatment with relapse during 6 month follow-up: 35% vs. 70% (denominators not clear)

Appendix E53. Trials of Low-Level Lasers Included in the APS/ACP Review

Author, Year, Title	Duration of Followup	Loss to Followup	Compliance to Treatment	Adverse Events and Withdrawals Due To Adverse Events	Comments
Basford, 1999 Laser therapy: a randomized, controlled trial of the effects of low-intensity Nd:YAG laser irradiation on musculoskeletal back pain	4 week treatment with follow-up 1 month after treatment end	2/63 (5.5%) chose not to participate 56/63 (89%) participated through follow-up	Not reported. Full compliance assumed, as treatment administered by medical provider per protocol.	"Side effects from treatment were negligible"	
Soriano, 1998 Gallium arsenide laser treatment of chronic low back pain: a prospective, randomized and double blind study	2 week treatment with 6 month follow-up	38/43 (88%) treatment evaluated 33/42 (79%) control evaluated	3/43 and 6/43 used NSAIDS and were excluded from analyses	No patient reported side effects that could be attributed to irradiation.	Number of patients evaluated at 6 months unclear. No ITT analysis at end of treatment.

Appendix E53. Trials of Low-Level Lasers Included in the APS/ACP Review

Author, Year, Title	Purpose of Study	Study Design	Inclusion Criteria	Exclusion Criteria	Number of Treatment and Control Subjects (number approached, number eligible, number enrolled)
Toya, 1994 Report on a computer-randomized double-blind computer trial to determine the effectiveness of the GaAIAs (830 NM) diode laser for pain attenuation in selected pain groups	To ascertain if infrared diode low reactive level laser therapy is effective for different types of pain	RCT	Not clearly stated	Not stated	Number approached and eligible not reported 130 enrolled; 41 with lumbar pain (other patients not reported here), 16 randomized to laser and 25 to sham
Klein, 1990 Low-energy laser treatment and exercise for chronic low back pain: double blind controlled trial	To test the efficacy of low-energy laser biostimulation combined with exercise.	RCT	Age 21 to 55 years, chronic back pain >1 year	Pregnancy, prior back surgery, more than ten pounds overweight, not involved in litigation or disability, acute exacerbations of chronic pain	24 interviewed 20 randomized, 10 to treatment and 10 to placebo

Appendix E53. Trials of Low-Level Lasers Included in the APS/ACP Review

Author, Year, Title	Subject Age, Gender, Diagnosis	Country and Setting	Sponsor	Measures
Toya, 1994 Report on a computer-randomized double-blind computer trial to determine the effectiveness of the GaAIAs (830 NM) diode laser for pain attenuation in selected pain groups	Mean age (all patients): 49.2 years Female gender: 46% Duration and intensity of pain: Not reported	Japan 2 outpatient clinics of medical university hospitals	Not reported	Before treatment, soon after treatment, and 1 day after the single treatment session: Subjective pain improvement (methods not specified) Objective pain improvement by physician assessment (methods not specified) Side effects (methods not specified)
Klein, 1990 Low-energy laser treatment and exercise for chronic low back pain: double blind controlled trial	Mean age: 44 vs. 41 Female gender: 75% overall Race: Not reported Duration of pain: 8.3 vs. 9.2 years Disability scores: 5.4 vs. 5.9 Baseline pain scores: 3.0 vs. 3.3	USA Clinic setting not reported	Santa Barbara Cottage Hospital and Sansum Medical Research Foundation	Visual analogue pain scores: 0 cm (absence of pain) to 7.5 cm (maximal pain), assessed 1 week before treatment and 1 month after treatment completion. Disability scores derived from a previously validated questionnaire with 24 items (Roland Morris) assessed 1 week before treatment and 1 month after treatment completion. Isotechnologies B-200: computerized isodynamic system to measure lumbar function. Measurements performed by physical therapist using standardized protocol. Range of motion, isometric torque, and isodynamic velocities in all 3 major axes. Measurements 1 week before treatment & 1 month after completion.

Appendix E53. Trials of Low-Level Lasers Included in the APS/ACP Review

Author, Year, Title	Type of Intervention	Results
Toya, 1994 Report on a computer-randomized double-blind computer trial to determine the effectiveness of the GaAIAs (830 NM) diode laser for pain attenuation in selected pain groups	A: Laser, 1 session treatment of 5 - 10 minutes (mean 9.18 + 1.1 minute). Laser: OhLase-3D1 (Proli, Japan, Ltd), a diode (GaAIAs) laser. Continuous wave output of 60 mW at 830 nm in the near infrared, delivered to target tissue using contact technique. Incident power density in contact mode fairly constant at approximately 3W/cm2. B: Sham laser	Laser vs. sham Treatment 'effective': 94% (15/16) vs. 48% (12/25)
Klein, 1990 Low-energy laser treatment and exercise for chronic low back pain: double blind controlled trial	A: Galllium-arsenide class 1 multihead pulsed-output infrared laser used with a frequency of 1000Hz, a pulse width of 200 nanoseconds, and a wavelength of 904 nanometers. External application over a series of standardized fields designed to include L4 to L5 and L5 to S1 apophyseal capsules, dorsolumbar fascia and interspinous ligaments, along with gluteal fascia and posterior sacroiliac ligaments. The mulithead has ten 2-W laser heads in a 12-cm linear array with permits simultaneous point stimulation of 1cm2 of tissue at each of 10 sites. 4 minute stimulation at each site, producing energy at each point of approximately 1.31/cm2. Approximately 20 minutes total stimulation time per patient. treatment 3 x per week for 4 weeks. Also standardized home exercise regimen. B: Sham laser + exercise	Laser vs. placebo, mean change in scores from baseline Pain (VAS 0 to 7.5): -1.3 vs. -1.2 Disability (RDQ): -1.8 vs. -3.0

Appendix E53. Trials of Low-Level Lasers Included in the APS/ACP Review

Author, Year, Title	Duration of Followup	Loss to Followup	Compliance to Treatment	Adverse Events and Withdrawals Due To Adverse Events	Comments
Toya, 1994 Report on a computer-randomized double-blind computer trial to determine the effectiveness of the GaAIAs (830 NM) diode laser for pain attenuation in selected pain groups	1 day after 1 session treatment	none	protocol design assured full compliance	Not reported	Outcome measures not adequately described
Klein, 1990 Low-energy laser treatment and exercise for chronic low back pain: double blind controlled trial	4 week treatment with follow-up 1 month after treatment end	none reported	Not reported	No patient in either group reported discomfort related to treatment. Unclear whether AEs were systematically assessed.	Treatment compliance not monitored Effectiveness of blinding not assessed

Appendix E53. Trials of Low-Level Lasers Included in the APS/ACP Review

Author, Year, Title	Purpose of Study	Study Design	Inclusion Criteria	Exclusion Criteria	Number of Treatment and Control Subjects (number approached, number eligible, number enrolled)
Longo, 1988 Treatment with 904 nm and 10600 nm laser of acute lumbago: double blind control	To test the efficacy of laser therapy on acute articular blockage.	RCT	Age 40 to 65, acute lumbago with degenerative or traumatic lesions visible in x-ray	Signs of neurological deficit. Fracture, luxation, hernia of nucleus pulposus	Number approached and eligible not reported. 120 randomized, 40 to each of Groups A, B and C

Appendix E53. Trials of Low-Level Lasers Included in the APS/ACP Review

Author, Year, Title	Subject Age, Gender, Diagnosis	Country and Setting	Sponsor	Measures
Longo, 1988 Treatment with 904 nm and 10600 nm laser of acute lumbago: double blind control	Mean age: Not reported Female gender: Not reported Race: Not reported Duration of pain: Not reported Baseline pain scores: not reported	Italy	Not reported	Spontaneous or induced pain. Pain intensity measured by Ritchie Scale Level of reflected analgesic vertebral deviation: indicated by angle of inclination in an anterior-posterior x-ray Functional limitation: percentage of normal movement of sacral-lumbar area Patients examined at treatment onset, after 3 and 5 applications, after 1 and 6 months, and after 1 year.

Appendix E53. Trials of Low-Level Lasers Included in the APS/ACP Review

Author, Year, Title	Type of Intervention	Results
Longo, 1988 Treatment with 904 nm and 10600 nm laser of acute lumbago: double blind control	A: Diode 904 nm laser, PW emission, 200 NSEC endurance for each impulse, spike shape, 3000 Hz frequency of impulse repetition, 72 W peak power. Divergence and expansion of the ray: solid half angle of 7.5 degree in vertical 12 degree position. Applications 1/day for 5 days, then another 5 on alternate days B: Sham laser - simulation laser irradiation C. 10,600 nm CO2 laser, PW, CW emission, divergence 1.5m Rad, 35 CW power, 30+/-5 W CW on tissue, exposure time: 0.01 - 99.99 sec. with resolution of 0.01 sec., pulsed wave: frequency 5-500 Hz duty cycle 30%, peak power: 150 W for impulses of 100 m length. Applications 1/day for 5 days, then another 5 on alternate days. Those with acute etiology received 10 applications. Those with acute crisis from chronic substrata received 15 treatments.	Group A (904 nm laser) vs. Group B (placebo) vs. Group C (10,600 nm laser) After 3 applications: 80% had complete disappearance of clinical features vs. none vs. 73% 15% had improvement vs. 5% vs. 20% 5% had no change vs. 15% exacerbation vs. 7.5% no change After 5 applications: 95% had complete disappearance of clinical features vs. none vs. 82.5% 2.5% had improvement vs. 30% vs. 7.5% 2.5% had no change vs. 60% vs. 5% None had exacerbation vs. 10% vs. 2.5% After 1 month: 95% had complete disappearance vs. 2.5% vs. 82.5% 2.5% had improvement vs. 35% vs. 10% 2.5% had no change vs. 50% vs. 7.5% None had exacerbation vs. 12.5% vs. none Relapse after 6 months: 30% vs. 87.5% vs. 27.5%

Appendix E53. Trials of Low-Level Lasers Included in the APS/ACP Review

Author, Year, Title	Duration of Followup	Loss to Followup	Compliance to Treatment	Adverse Events and Withdrawals Due To Adverse Events	Comments
Longo, 1988 Treatment with 904 nm and 10600 nm laser of acute lumbago: double blind control	1 year after treatment end	Not reported	Not reported	Not reported	

Please see Appendix C. Included Studies for full study references.

Appendix E54. Data Abstraction of Randomized Controlled Trials of Low-Level Lasers

Author, Year	Country Number of Centers and Setting	Inclusion Criteria	Number Randomized, Analyzed Attrition	Intervention	Study Participants	Duration of Pain (acute, subacute, chronic)
Ay 2010	Turkey Single-center	Acute of chronic low back pain Excluded: neurological deficit, spondylosis, spinal stenosis, infection, malignant spinal disease, previous spinal surgery, pregnancy	Randomized: 80 Analyzed: 80 Attrition: 0% (0/80)	Acute LBP A. GaA1As laser, 850 nm + heat 5 times/week for 3 weeks (n=20) B. Sham laser + heat 5 times/week for 3 weeks (n=20) Chronic LBP A. GaA1As laser 850 nm + heat 5 times/week for 3 weeks (n=20) B. Sham laser + heat 5 times/week for 3 weeks (n=20)	A vs. B: Acute LBP Mean age 48 vs. 45 years 30% vs. 40% female Pain, VAS: 6.7 vs. 6.15 Pain, patient global assessment: 6.45 vs. 5.0 Pain, physician global assessment: 6.6 vs. 6.15 Disability, RDQ: 13.2 vs. 12.6 Disability, Modified ODI: 19.8 vs. 20.8 A vs. B: Chronic LBP Mean age 52 vs. 55 years 55% vs. 45% female Pain, VAS: 6.0 vs. 6.6 Pain, patient global assessment: 5.65 vs. 6.05 Pain, physician global assessment: 5.8 vs. 6.3 Disability, RDQ: 15.1 vs. 15.6 Disability, Modified ODI: 23.9 vs. 24.65	Acute: 2 vs. 2 months Chronic: 50 vs. 48 months
Djavid 2007	Iran Single-center	Age 20-60 years with low back pain for at least 12 weeks Excluded: degenerative disc disease, herniation, fracture, spondylosis, spinal stenosis, neurologic deficits, systemic or psychiatric illness, pregnancy	Randomized: 61 Analyzed: 43 Attrition: 30% (18/61)	A. GaA1As, 810 nm laser 2 times/week for 6 weeks (n=16) B. GaA1As laser, 810 nm 2 times/week for 6 weeks + exercise (n=19) C. Sham laser 2 times/week for 6 weeks + exercise (n=18)	A vs. B vs. C Mean age 40 vs. 38 vs. 36 years 56% vs. 37% vs. 17% female Race not reported Pain, VAS 7.3 vs. 6.2 vs. 6.3 Disability, ODI 33.0 vs. 34.0 vs. 31.8	Chronic: mean 29 vs. 29 vs. 25 months

Appendix E54. Data Abstraction of Randomized Controlled Trials of Low-Level Lasers

Author, Year	Outcome Measures	Duration of Followup	Results (list results for acute, subacute and chronic separately)	Adverse Events Including Withdrawals	Funding Source	Quality Rating
Ay 2010	Pain: VAS, scale 0-10 Pain: patient global assessment, scale 0-10 Pain: physician global assessment, scale 0-10 Disability: RDI, scale 0-24 Disability: Modified ODI, scale 0-50	3 weeks	A vs. B: Acute LBP Pain, VAS mean change from baseline: -4.0 vs. -4.15; p=0.07 Pain, patient global assessment mean change from baseline: -3.9 vs. -4.7; p=0.006 Pain, physician global assessment mean change from baseline: -4.1 vs. -4.2; p=-0.71 Disability, RDQ mean change from baseline: -6.0 vs. -5.65; p=0.39 Disability, Modified ODI mean change from baseline: -8.2 vs. -8.7; p=0.15 A vs. B: Chronic LBP Pain, VAS mean change from baseline: -3.35 vs. -3.95; p=0.03 Pain, patient global assessment mean change from baseline: -3.3 vs. -3.9; p=0.11 Pain, physician global assessment mean change from baseline: -3.15 vs. -4.05; p=0.01 Disability, RDQ mean change from baseline: -6.7 vs. -4.65; p=<0.0001 Disability, Modified ODI mean change from baseline: -9.6 vs. -6.2; p; p<0.0001	Not reported	Not reported	Good
Djavid 2007	Pain: VAS, scale 0-10 Disability: ODI, scale 0-50	12 weeks	A vs. B vs. C Pain, VAS: 4.4 vs. 2.4 vs. 4.3; A vs. B, p=0.002; A vs. C, p=0.87; B vs. C, p=0.0005; mean change from baseline -2.9 vs. -3.8 vs. -2.0 Disability, ODI: 20.8 vs. 16.8 vs. 24.1; A vs. B, p=0.006; A vs. C, p=0.06; B vs. C, p=0.0001	No adverse events in any group (data not shown)	Not reported	Fair

Appendix E54. Data Abstraction of Randomized Controlled Trials of Low-Level Lasers

Author, Year	Country Number of Centers and Setting	Inclusion Criteria	Number Randomized, Analyzed Attrition	Intervention	Study Participants	Duration of Pain (acute, subacute, chronic)
Jovicic 2012	Serbia Single-center	Acute, clinically diagnosed LBP (duration <4 weeks) Excluded: chronic low back pain or previous surgery	Randomized: 66 Analyzed: 66 Attrition: 0% (0.66)	A. 904 nm laser, 0.1 joule per point (0.4 points/day; n=22) B. 904 nm laser, 1.0 joule per point (4.0 points/day; n=22) C. 904 nm laser, 4.0 joules per point (16.0 points/day; n=22)	A vs. B vs. C Mean age 47 vs. 44 vs. 45 years Gender, race not reported Lumbar pain, VAS: 7 vs. 7 vs. 6.5	Acute: mean duration not reported; inclusion criteria required <4 weeks duration of symptoms

Appendix E54. Data Abstraction of Randomized Controlled Trials of Low-Level Lasers

Author, Year	Outcome Measures	Duration of Followup	Results (list results for acute, subacute and chronic separately)	Adverse Events Including Withdrawals	Funding Source	Quality Rating
Jovicic 2012	Pain: VAS scale 0-10 Function: Activities of Daily Living	2 weeks	A vs. B vs. C Lumbar pain, VAS mean change (results depicted graphically): -3 vs. -3 vs. -3.5; p>0.05 Function, Activities of Daily Life: walking, mean change from baseline in proportion able to complete activity - all outcomes A or B vs. C p=0.007 Able to walk: Not able to walk >1 hour: 4.5% vs. 4.6% vs. 13.6% Not able to walk >30 mins: 18.2% vs. 13.6% vs. 41% Not able to walk >10 mins: -4.6% vs. -13.7% vs. -18.2% Only able to walk a few steps: -27.3% vs. -22.8% vs. -31.8% Not able to walk at all: -4.5% vs. -4.5% vs. -9.1% Function, Activities of Daily Living: sitting, mean change from baseline in proportion able to complete activity - all outcomes A or B vs. C p=0.005 Able to sit: 4.6% vs. 4.5% vs. 4.5% Not able to sit >1 hour: 27.3% vs. 0% vs. 31.9% Not able to sit >30 mins: 13.7% vs. 50% vs. 0% Not able to sit > a few mins: -40.9% vs. -31.9% vs. -36.4% Not able to sit at all: -4.5% vs. -22.8% vs. -13.6% Function, Activities of Daily Living: standing, mean change from baseline in proportion able to complete activity - all outcomes A or B vs. C p=0.013 Able to stand: 9.1% vs. 0% vs. 13.6% Able to stand with pain: 4.6% vs. 22.7% vs. 22.8% Not able to stand >1 hour: 13.6% vs. 13.6% vs. 36.4% Not able to stand >30 mins: 27.3 vs. 18.2% vs. 9.1% Not able to stand >10 mins: -31.8% vs. -18.2% vs. -31.8% Not able to stand at all: -22.8% vs. -36.4% vs. -31.8%	No systemic or local side effects reported (data not shown)	Not reported	Fair

Appendix E54. Data Abstraction of Randomized Controlled Trials of Low-Level Lasers

Author, Year	Country Number of Centers and Setting	Inclusion Criteria	Number Randomized, Analyzed Attrition	Intervention	Study Participants	Duration of Pain (acute, subacute, chronic)
Konstantinovic 2010	Serbia Single-center	Acute LBP (symptomatic <4 weeks) and unilateral radiculopathy Excluded: Use of oral or injected corticosteroids within month preceding study entry or previous surgery	Randomized: 546 Analyzed: 546 Attrition: 0% (0/546)	A. 904 nm laser 5 times/week for 3 weeks + nimesulide 200 mg/day (n=182) B. Sham laser 5 times/week for 3 weeks + nimesulide 200 mg/day (n=182) C. Nimesulide 200 mg/day (n=182)	A vs. B vs. C Mean age 44 vs. 42 vs. 45 years 59% vs. 58% vs. 57% female Race not reported Lumbar pain, VAS: 66 vs. 65 vs. 67 Disability, ODI: 32 vs. 32 vs. 31 Quality of life, SF-36 PCS: 10 vs. 10 vs. 10 Quality of life, SF-36 MCS: 12 vs. 12 vs. 12	Acute: mean 15 vs. 18 vs. 16 days

Appendix E54. Data Abstraction of Randomized Controlled Trials of Low-Level Lasers

Author, Year	Outcome Measures	Duration of Followup	Results (list results for acute, subacute and chronic separately)	Adverse Events Including Withdrawals	Funding Source	Quality Rating
Konstantinovic 2010	Pain: VAS, scale 0-100 Disability: ODI, scale 0-50 Quality of life: SF-36 physical and mental component scores, scale 0-100; higher score = more disability	3 weeks	A vs. B vs. C Lumbar pain, VAS mean change: -30 vs. -15.7 vs. -20.8; p<0.01 for all comparisons Disability, ODI mean change: -12 vs. -6.5 vs. -10; p<0.01 for all comparisons Disability, ODI proportion improved (defined as change from moderate to minimal disability category): 72% (151/182) vs. 54% (98/182) vs. 18% (33/182); A vs. B, RR 1.54 (95% CI 1.33 to 1.79); A vs. C, RR 4.58 (95% CI 3.34 to 6.27); B vs. C, RR 2.97 (95% CI 2.12 to 4.16) Quality of life, SF-36 PCS: -4 vs. -2 vs. -3; A vs. B, A vs. C p<0.01; B vs. C p=0.06 Quality of life, SF-36 MCS: -6 vs. -3 vs. -4; p<0.01 for all comparisons	Two withdrawals due to worsening pain; intervention group(s) not reported	Not reported	Good

Please see Appendix C. Included Studies for full study references.

Appendix E55. Trials of Short-Wave Diathermy Included in the APS/ACP Review

Author, Year, Title	Purpose of Study	Study Design	Inclusion Criteria	Exclusion Criteria	Number of Treatment and Control Subjects (number approached, number eligible, number enrolled)
Sweetman, 1993 A randomized controlled trial of exercises, short wave diathermy, and traction for low back pain, with evidence of diagnosis-related response to treatment	To evaluate the efficacy of short wave diathermy, exercise, and traction in patients with low back pain of unspecified duration	RCT	Low back pain severe enough to warrant physiotherapy, age >12 years, pain >1 week	"Red flags", pregnancy, rheumatoid arthritis or metabolic bone disease, presence of metal in area of short-wave, other treatment thought indicated, treatments felt contraindicated, treatment other than oral meds, other 'relative' contraindications including improvement, psychosocial factors	579 screened 400 randomized (100 to short-wave diathermy, 100 to exercises, 100 to traction, 100 to no treatment)
Gibson, 1985 Controlled comparison of short-wave diathermy treatment with osteopathic treatment in non-specific low back pain	To evaluate efficacy of short wave diathermy vs. osteopathic manipulation	RCT	Low back pain 2 to 12 months	Signs of radiculopathy, inflammatory, metabolic, or neoplastic spinal disease, spondylolysis, spondylolisthesis, treatment other than analgesics	Number approached and eligible not reported 109 randomized (34 to short wave diathermy, 41 to manipulation, and 34 to sham diathermy)
Rasmussuen, 1979 Manipulation in treatment of low back pain (--a randomized clinical trial)	To evaluate efficacy of spinal manipulation versus short-wave diathermy	RCT	Low back pain <3 weeks without signs of radiculopathy, no treatment other than analgesics	Contraindication to manipulation	Number approached and eligible not reported 26 randomized, 2 lost to follow-up (12 to manipulation and 12 to short-wave diathermy)

Appendix E55. Trials of Short-Wave Diathermy Included in the APS/ACP Review

Author, Year, Title	Subject Age, Gender, Diagnosis	Country and Setting	Sponsor	Measures
Sweetman, 1993 A randomized controlled trial of exercises, short wave diathermy, and traction for low back pain, with evidence of diagnosis-related response to treatment	Mean age: 40 vs. 42 vs. 40 vs. 41 Female gender: Not reported Non-white race: Not reported "Bedridden": 39% vs. 43% vs. 37% vs. 42% Duration >10 months: 17% vs. 10% vs. 22% vs. 17%	UK Single center Physical therapy clinic	Not reported	Global effect (better, same, worse)
Gibson, 1985 Controlled comparison of short-wave diathermy treatment with osteopathic treatment in non-specific low back pain	Mean age: 35 vs. 34 vs. 40 years Female gender: 47% vs. 51% vs. 32% Non-white race: Not reported Duration of pain: 18 vs. 16 vs. 17 weeks Pain worsening on presentation: 41% vs. 27% vs. 23%	UK Number of centers and setting unclear	Not reported	Pain: 0 to 100 VAS Spinal tenderness: 0 (none) to 3 (severe) Analgesics use Ability to work
Rasmussuen, 1979 Manipulation in treatment of low back pain (--a randomized clinical trial)	Men age: 35 years (not reported by intervention group) Female gender: Not reported Non-white race: Not reported Duration or severity of pain: Not reported	Denmark Single center Physical medicine and rheumatology clinic	Not reported	"Fully restored"=no pain, normal function, no objective signs of disease, and fit to work

Appendix E55. Trials of Short-Wave Diathermy Included in the APS/ACP Review

Author, Year, Title	Type of Intervention	Results
Sweetman, 1993 A randomized controlled trial of exercises, short wave diathermy, and traction for low back pain, with evidence of diagnosis-related response to treatment	A: Short wave diathermy 20 minutes 3 times weekly B: Extension exercises C: Traction 3 times weekly D: No treatment 2 weeks	Short wave diathermy vs. extension exercises vs. traction vs. no treatment Global effect "better": 39% (39/100) vs. 45% (45/100) vs. 49% (49/100) vs. 37% (37/100)
Gibson, 1985 Controlled comparison of short-wave diathermy treatment with osteopathic treatment in non-specific low back pain	A: Short wave diathermy 3 times weekly B: Osteopathic manipulation 1 time weekly C: Detuned (sham) diathermy 3 times weekly 4 weeks	Short wave diathermy vs. osteopathic manipulation vs. detuned (sham) diathermy Median daytime pain score (0 to 100) at 2 weeks: 35 vs. 25 vs. 28 Median daytime pain score (0 to 100) at 12 weeks: 25 vs. 13 vs. 6 Proportion free of pain at 2 weeks: 35% vs. 25% vs. 28% Proportion free of pain at 12 weeks: 37% vs. 42% vs. 44% Proportion needing analgesics at 2 weeks: 22% vs. 18% vs. 32% Proportion needing analgesics at 12 weeks: 7% vs. 18% vs. 22% Proportion unable to work or with modified activities at 2 weeks: 31% vs. 13% vs. 38% Proportion unable to work or with modified activities at 12 weeks: 7% vs. 5% vs. 19%
Rasmussuen, 1979 Manipulation in treatment of low back pain (--a randomized clinical trial)	A: Short wave diathermy 3 times a week B: Spinal manipulation 3 times a week (rotational manipulation in the pain-free direction) 2 weeks	Short wave diathermy vs. spinal manipulation Proportion 'fully restored" by 14 days: 25% (3/12) vs. 92% (11/12)

Appendix E55. Trials of Short-Wave Diathermy Included in the APS/ACP Review

Author, Year, Title	Duration of Followup	Loss to Followup	Compliance to Treatment	Adverse Events and Withdrawals Due To Adverse Events
Sweetman, 1993 A randomized controlled trial of exercises, short wave diathermy, and traction for low back pain, with evidence of diagnosis-related response to treatment	2 weeks	51/400 (13%)	22/400 didn't attend treatment	Not assessed
Gibson, 1985 Controlled comparison of short-wave diathermy treatment with osteopathic treatment in non-specific low back pain	12 weeks	13/109 (12%)	Not reported	Not assessed
Rasmussuen, 1979 Manipulation in treatment of low back pain (--a randomized clinical trial)	2 weeks	2/26 (8%)	Not reported	Not assessed

Please see Appendix C. Included Studies for full study references.

Appendix E56. Data Abstraction of Randomized Controlled Trials of Diathermy

Author, Year	Country Number of Centers and Setting	Inclusion Criteria	Number Randomized, Analyzed Attrition	Intervention	Study Participants	Duration of Pain (acute, subacute, chronic)
Ahmed, 2009	Bangladesh Single center	20 to 80 years of age, low back pain ≥3 months Exclude: Traumatic low back pain, inflammatory back pain, back pain with complications	Randomized: Unclear Analyzed: 97 Attrition: Not reported	A: Short wave diathermy (n=47) B: Detuned (sham) diathermy (n=50) 15 minute sessions, 3 times a week for six weeks	Mean age: 40 years (overall) Female: Not reported Race: Not reported Baseline pain (mean, 0-34 [Lattinen's score plus tenderness score plus 0-10 VAS]): 20.4 vs. 20.1 Back-specific function: Not reported	Chronic (>3 months), mean duration not reported
Shakoor, 2008	Bangladesh Single center	30 to 70 years of age, low back pain >3 months Exclude: Traumatic low back pain, back pain with complications, infection on the skin over the back area	Randomized: "About" 127 Analyzed: 102 Attrition: Unclear	A: Short wave diathermy: 27.33 MHz, wavelength 11 m (n=50) B: Detuned (sham) diathermy (n=52) 15 minute sessions, 3 times a week for six weeks Both groups also underwent extension and strengthening exercises (10 repetitions twice daily for 6 weeks) and received Naprosyn 250 mg po bid	Mean age: 44.5 vs. 40.0 years Female: 59% (overall) Race: Not reported Baseline pain (mean, 0-34 [Lattinen's score plus tenderness score plus 0-10 VAS]): 15.2 vs. 15.6 Back-specific function: Not reported	Chronic (>3 months), mean 40 vs. 35 months

Appendix E56. Data Abstraction of Randomized Controlled Trials of Diathermy

Author, Year	Duration of Followup	Results (list results for acute, subacute, and chronic separately)	Adverse Events Including Withdrawals	Funding Source	Quality
Ahmed, 2009	6 weeks (at end of therapy)	A vs. B Pain (mean, 0-34 [Lattinen's score (0-20) plus tenderness score (0-4) plus 0-10 VAS]): 17.8 vs. 18.8 at w 1 (p=0.14), 15.3 vs. 17.6 at w 2 (p=0.01), 11.1 vs. 15.0 at w 4 (p<0.05), 6.4 vs. 13.4 at w 6 (p<0.05)	Not reported	Not reported	Poor
Shakoor, 2008	6 weeks (at end of therapy)	A vs. B Pain (mean, 0-34 [Lattinen's score (0-20) plus tenderness score (0-4) plus 0-10 VAS]): 13.9 vs. 14.5 at w 1 (p=0.31), 11.9 vs. 12.4 at w 2 (p=0.33), 10.3 vs. 11.8 at w 4 (p=0.02), 9.66 vs. 11.6 at w 6 (p<0.05)	Not reported	Not reported	Poor

Please see Appendix C. Included Studies for full study references.

Appendix E57. Data Abstraction of Systematic Reviews of Lumbar Supports

Author, Year	Comparison	Data Sources	Number and Type of Studies	Interventions and Number of Patients	Methods for Rating Methodological Quality of Primary Studies	Methods for Synthesizing Results of Primary Studies
van Duijvenbode 2008	Lumbar supports vs. no intervention Lumbar supports vs. other active treatment One type of lumbar support vs. another	PubMed, CCRCT, EMBASE, CINAHL (through December 2006), Current Contents (through September 1999), reference lists, expert recommendation; no language restrictions reported	8 RCTs; 7 English-language, 1 German language Chronic pain (3 trials), mixed acute, subacute and chronic pain (4 trials); duration of pain not reported in 1 trial	A. Lumbar supports (n=418) B. Other active interventions (spinal manipulation therapy, n=186; other physiotherapy, n=114; massage, n=37; TENS, n=28; exercise [strength training], n=21; analgesics, n=113; nonsupportive corset, n=10) C. No support (n=309) *One trial that randomized 79 participants to support or no support did not report number in each treatment group*	Cochrane Back Review Group criteria (2003)	Qualitative analysis judging level of evidence (strong, moderate, limited conflicting or no evidence) due to no poolable data

Appendix E57. Data Abstraction of Systematic Reviews of Lumbar Supports

Author, Year	Results	Adverse Events	Quality
van Duijvenbode 2008	A vs. B (specified below; no data reported for any outcome) Mixed population (acute, subacute and/or chronic) Pain: 3 trials (1 higher quality, 2 lower quality) found no difference between lumbar support and traction, spinal manipulation, exercise, physiotherapy or TENS in short-term pain Function: 1 higher quality trial found no difference between lumbar support and massage using ODI; difference was significant (favoring lumbar support) using RMDQ Return to work: No difference between lumbar support and traction, spinal manipulation, or exercise Global improvement: 2 lower-quality trials found no difference between lumbar support and other active treatments in global improvement A vs. C (no data reported for any outcome) Chronic population 1 lower-quality trial found no difference for pain and function outcomes after 2 months treatment Acute and subacute population Pain: 3/4 trials (1 higher quality, 2 lower quality) found no difference in short-term pain reduction; 1 lower quality trial found significant difference in short-term pain with use of lumbar support Function: 3 trials (1 higher quality, 2 lower quality) found significant effect in favor of lumbar support for short-term functional status Return to work: Mixed evidence from 2 lower-quality trials; one found no difference, one found an effect favoring lumbar support Global improvement: 2 lower-quality trials reported no difference in short-term global improvement (A+B) vs. A (no data reported for any outcome) Chronic population 1 lower quality trial comparing lumbar support + exercise (muscle strengthening) with lumbar support alone found no difference in short- or long-term pain or function 1 lower quality trial comparing lumbar support + nonsupportive corset to nonsupportive corset alone found significant effects in favor of lumbar support + nonsupportive corset in short-term pain and back-specific function A vs. A Chronic population 1 lower-quality trial found no difference between lumbar support, flexible corset and semi-rigid corset in short-term pain or function	Not reported	Good

Please see Appendix C. Included Studies for full study references.

Appendix E58. Data Abstraction of Randomized Controlled Trials of Lumbar Support

Author, Year	Country Number of Centers and Setting	Inclusion Criteria	Number Randomized, Analyzed Attrition	Intervention
Studies published since the APS and Cochrane reviews				
Calmels 2009	France Single center	Age 20 to 60 years, duration of LBP 1 to 3 months Excluded: presence of radicular pain, prior surgery or lumbar belt use (within 6 months), traumatic LBP, chronic CV or respiratory disease, contraindication to NSAID	Randomized: 217 Analyzed: 197 Attrition: 9% (20/217)	A. Lumbar support (n=102) 5-8 hours/day, 3-5 days/week (varied according to study timepoint; hours of use/week decreased over time) B. No lumbar support (n=95)
Oleske 2007	United States Multicenter	Workers identified through a corporate Health Information System having nontraumatic, work-related low back disorder within 8 weeks of study entry Excluded: Concomitant work-related injury or illness	Randomized: 433 Analyzed: 433 Attrition: 0% (0/433)	A. Lumbar support + education (n=222), timing of support use not reported B. Education only (n=211)

Appendix E58. Data Abstraction of Randomized Controlled Trials of Lumbar Support

Author, Year	Study Participants	Duration of Pain (acute, subacute, chronic)	Duration of Followup	Results (list results for acute, subacute and chronic separately)
Studies published since the APS and Cochrane reviews				
Calmels 2009	Population characteristics not reported by treatment group Mean age 43 years 45% female Race not reported A vs. B Population characteristics reported by treatment group Mean pain (VAS, scale 0-100) 60.9 vs. 59.7 Mean function (EIFEL score, scale 0-24; higher score = more disability) 10.3 vs. 10.1	Subacute; mean duration not reported but inclusion criteria required pain duration 1-3 months at baseline	3 months (90 days)	A vs. B Pain, mean change in VAS, day 30: -26.8 (SD 18.2) vs. -21.3 (SD 18.7); p=0.04 Pain, mean change in VAS, day 90: -41.5 (SD 21.5) vs. -32.0 (SD 20.0); p=0.002 Function, mean change in EIFEL score, day 30: -5.4 (SD 4.1) vs. -4.0 (SD 4.3); p=0.02 Function, mean change in EIFEL score, day 90: -7.6 (SD 4.4) vs. -6.1 (SD 4.7); p=0.02
Oleske 2007	A vs. B Mean age 46 vs. 46 years 17% vs. 24% female Race: 66% vs. 67% white; 34% vs. 33% non-white 67% vs. 69% onset of LBP <2 weeks prior to study entry Mean pain (VAS, scale 0-10) 4.09 vs. 4.18 Mean function (Oswestry, scale 0-100; higher score = more disability) 24.4 vs. 24.5	Acute or subacute; mean duration not reported but inclusion criteria required pain duration <8 weeks at baseline	1 year	A vs. B Pain, coefficient of change (group A=reference group): -0.248 days; p=0.3 Function, coefficient of change (group A=reference group): -0.298 days; p=0.8 Overall conclusion: no difference between treatment groups for pain or function outcomes

Appendix E58. Data Abstraction of Randomized Controlled Trials of Lumbar Support

Author, Year	Adverse Events Including Withdrawals	Funding Source	Quality	Comments
Studies published since the APS and Cochrane reviews				
Calmels 2009	Not reported	No external funding	Fair	
Oleske 2007	Not reported	UAW-GM National Joint Committee on Health and Safety	Fair	

Appendix E58. Data Abstraction of Randomized Controlled Trials of Lumbar Support

Author, Year	Country Number of Centers and Setting	Inclusion Criteria	Number Randomized, Analyzed Attrition	Intervention
Sato 2012	Japan	Chronic low back pain patients attending a university hospital clinic in Japan Excluded: LBP due to infection, osteoporosis, or malignancy	Randomized: 50 Analyzed: 40 Attrition: 20% (10/50)	A. Lumbar support (corset; n=not reported) worn during all waking hours for 6 months except during bathing B. No lumbar support (n=not reported)

Appendix E58. Data Abstraction of Randomized Controlled Trials of Lumbar Support

Author, Year	Study Participants	Duration of Pain (acute, subacute, chronic)	Duration of Followup	Results (list results for acute, subacute and chronic separately)
Sato 2012	*Population characteristics not reported by treatment group* Mean age not reported; range 30 to 78 years 50% female Race not reported Mean pain and function score not reported	Chronic; mean duration not reported but inclusion criteria required pain duration >3 months at baseline	6 months	A vs. B Function, Japanese Orthopedic Association (JOA) criteria (includes patient-assessment of pain and function), 1 month: significant difference in JOA score, favoring lumbar support: p<0.01 (no data shown); no significant difference between groups at 3 and 6 months

Appendix E58. Data Abstraction of Randomized Controlled Trials of Lumbar Support

Author, Year	Adverse Events Including Withdrawals	Funding Source	Quality	Comments
Sato 2012	Not reported	Not reported	**Fair**	

Please see Appendix C. Included Studies for full study references.

Appendix E59. Data Abstraction of Systematic Reviews of Traction

Author, Year	Comparison	Data Sources	Number and Type of Studies	Interventions and Number of Patients	Methods for Rating Methodological Quality of Primary Studies	Methods for Synthesizing Results of Primary Studies
Wegner 2013	Traction vs. sham, placebo or no treatment Traction vs. other active treatments One type of traction vs. another type of traction	MEDLINE, CCRCT, EMBASE, CINAHL, Cochrane Back Group Specialized Register (all through August 2012)	32 RCTs (n=2,762) Traction vs. sham, placebo or no treatment: 13 trials Traction vs. other treatments: 15 trials Traction vs. traction: 5 trials Chronic LBP: 10 trials Subacute LBP: 1 trial Mixed acute, subacute and chronic: 17 trials Unspecified duration of LBP: 5 trials	A. Traction A1. Traction + physiotherapy B. Sham, placebo or no treatment B1. Physiotherapy alone C. Other interventions (exercise, interferential therapy, massage, balneotherapy)	Cochrane Back Review Group criteria (2009)	Qualitative synthesis (due to heterogeneity of outcomes reported) including study risk of bias; results pooled (qualitative analysis) when possible

Appendix E59. Data Abstraction of Systematic Reviews of Traction

Author, Year	Results	Adverse Events	Quality Rating	Comments
Wegner 2013	A vs. B Difference in LBP population with or without radiation Pain, 3-5 weeks (2 trials): -18.49 (95% CI -24.12 to -12.87) Pain, 6-12 weeks (1 trial): 0.30 (95% CI -9.91 to 10.51) Pain, 6 months (1 trial): -0.5 (95% CI -11.55 to 10.55) Pain, 1 year (1 trial): -9.10 (95% CI -19.32 to 1.12) Functional status, 3-5 weeks (1 trial): -1.30 (95% CI -2.90 to 0.30) Functional status, 6-12 weeks (1 trial): 0.10 (95% CI -1.76 to 1.96) Functional status, 6 months (1 trial): 0.70 (95% CI -1.16 to 2.56) Global improvement, 3-5 weeks (2 trials): -0.03 (95% CI -0.17 to 0.12) Global improvement, 6-12 weeks (2 trials): 0.03 (95% CI -0.12 to 0.18) Global improvement, 6 months (1 trial): 0.02 (95% CI -0.14 to 0.18) Return to work, 3-5 weeks (1 trial): -1.80 (95% CI -5.51 to 1.91) Return to work, 6-12 weeks (1 trial): -4.30 (95% CI -14.71 to 6.11) Return to work, 6 months (1 trial): -8.00 (95% CI -26.99 to 10.99) Difference in LBP population with radiation Pain, 1-2 weeks (2 trials): 2.93 (95% CI -14.73 to 20.59) Global improvement, 1-2 weeks (4 trials): 0.13 (95% CI 0.04 to 0.22) Global improvement, 3-5 weeks (2 trials): 0.27 (95% CI 0.12 to 0.43) Global improvement, 12-16 weeks (1 trial): 0.06 (95% CI -0.16 to 0.28) Return to work, 2 years (1 trial): 0.15 (95% CI -0.15 to 0.45) Difference in LBP population without radiation Pain intensity, 12-16 weeks: -4.00 (95% CI -17.65 to 9.65) A vs. A (one traction type versus another) Difference in LBP population with or without radiation Global improvement, 1-2 weeks: -0.08 (95% CI -0.46 to 0.30; static traction vs. intermittent traction); 0.53 (95% CI 0.32 to 0.73; auto traction vs. mechanical traction) Difference in LBP population with radiation Pain, 1-2 weeks (3 trials): 6.58 (-2.77 to 15.93) Global improvement, 1-2 weeks (1 trial): -0.16 (-0.40 to 0.09)	Adverse events were reported in 11/32 studies; 4 reported no adverse events. A vs. B Aggravation of symptoms (2 trials): 24% (9/38) vs. 20% (4/20); RR 1.18 (95% CI 0.42 to 3.37); 12% (5/43) vs. 2% (1/43); RR 5.00 (95% CI 0.61 to 41) Subsequent surgery (1 trial): 9% (7/82) vs. 0% (0/60); RR 11 (95% CI 0.64 to 189) A vs. A Increased pain (2 trials): Inversion vs. conventional traction - 79% (11/14) vs. 15% (2/13); RR 5.11 (95% CI 1.39 to 19); Static vs. intermittent traction - 31% (4/13) vs. 15% (2/13); RR 2.00 (95% CI 0.44 to 9.08) A1 vs. B1 Worsening of symptoms (1 trial): 25% (5/21) vs. 37% (8/21); RR 0.63 (95% CI 0.24 to 1.60) A vs. C Temporary deterioration (1 trial): Traction vs. exercise - 17% (4/24) vs. 15% (4/26); RR 1.08 (95% CI 0.30 to 3.86)	Good	Results not stratified according to duration of LBP

Appendix E59. Data Abstraction of Systematic Reviews of Traction

Author, Year	Results	Adverse Events	Quality Rating	Comments
Wegner 2013 (cont.)	A1 vs. B1 Difference in LBP population with or without radiation Pain, 1-2 weeks (1 trial): 0.00 (95% CI -7.61 to 7.61) Pain, 12-16 weeks (1 trial): 5.00 (95% CI -5.67 to 15.67) Functional status, 1-2 weeks (1 trial): 3.90 (-1.91 to 9.71) Functional status, 12-16 weeks (1 trial): 4.00 (95% CI -2.78 to 10.78) Global improvement, 1-2 weeks (1 trial): 0.05 (95% CI -0.25 to 0.35) Global improvement, 12-16 weeks (1 trial): 0.53 (95% CI 0.28 to 0.79) Difference in LBP population with radiation Pain, 1-2 weeks (2 trials): -7.96 (95% CI -16.53 to 0.61) Pain, 6 weeks (1 trial): 2.00 (95% CI -10.02 to 14.02) Functional status, 1-2 weeks (2 trials): -0.08 (95% CI -0.49 to 0.32) Functional status, 6-12 weeks (1 trial): 0.14 (95% CI -0.35 to 0.63) Functional status, 12-16 weeks (1 trial): 0.43 (95% CI -0.30 to 1.16) Functional status, 6 months (1 trial): 0.18 (95% CI -0.54 to 0.90) Global improvement: No pooled estimates for any timepoint. Results from three individual trials showed no significant difference between groups from timepoints ranging from 1-2 to 12-16 weeks. Return to work, 3-5 weeks (1 trial): OR 1.41 (95% CI 0.61 to 3.28) A vs.C Difference in LBP population with or without radiation Pain: No pooled estimates for any timepoint. Results from four individual trials were mixed for all timepoints ranging from 1-2 weeks to 1 year Functional status, 1-2 weeks (1 trial): -0.06 (95% CI -0.40 to 0.27) Functional status, 3-5 weeks (1 trial): 0.20 (95% CI -0.05 to 0.46) Functional status, 12-16 weeks (2 trials): -0.03 (95% CI -0.26 to 0.21) Functional status, 6 months (1 trial): 0.15 (95% CI -0.16 to 0.45) Functional status, 1 year (1 trial): 0.04 (95% CI -0.25 to 0.34) Global improvement: No pooled estimates for any timepoint. Results from three individual trials were mixed for timepoints ranging from 1-2 to 12-16 weeks. Difference in LBP population with radiation Pain: No pooled estimates for any timepoint. Results from two individual trials showed no significant difference between groups from timepoints ranging from 1-2 to 12-16 weeks. Functional status: No pooled estimates for any timepoint. Results from two individual trials showed no significant difference between groups from timepoints ranging from 1-2 to 12-16 weeks. Global improvement: No pooled estimates for any timepoint. Results from two individual trials showed no significant difference between groups from timepoints ranging from 1-2 and 3-5 weeks.			

Appendix E59. Data Abstraction of Systematic Reviews of Traction

Please see Appendix C. Included Studies for full study references.

Appendix E60. Data Abstraction of Randomized Controlled Trials of Traction

Author, Year	Country Number of Centers and Setting	Inclusion Criteria	Number Randomized, Analyzed Attrition	Intervention	Study Participants
Studies published since the APS and Cochrane reviews					
Diab 2012 and Diab 2013	Egypt Single center	Chronic low back pain (duration ≥3 months) with Cobb angle <40° Excluded: RA, OA, spinal stenosis, inability to tolerate lumbar extension, scoliotic or other lower extremity deformity	Randomized: 80 Analyzed: unclear Attrition: unclear (16% [13/80] withdrawn from study at 6 month followup)	A. Traction, radiation and stretching 3 times/week for 10 weeks (n=40) B. Radiation and stretching 3 times/week for 10 weeks (n=40)	A vs. B Mean age 46 vs. 46 years 45% vs. 43% female Race not reported Prior LBP treatment 100% vs. 100% Pain, VAS: 6.0 vs. 5.5 Disability, ODI: 32.4 vs. 31.1
Moustafa 2013	Egypt Single center	Chronic low back pain (duration ≥3 months) with Harrison angle <39°, unilateral leg pain, mild to moderate disability per ODI Excluded: history of back surgery, systemic illness including cancer, RA, OA, spinal stenosis, inability to tolerate lumbar extension, scoliotic or other lower extremity deformity	Randomized: 64 Analyzed: 58 Attrition: 9% (6/64)	A. Traction, hot packs and interferential therapy 3 times/week for 10 weeks (n=32) B. Hot packs and interferential therapy 3 times/week for 10 weeks (n=32)	A vs. B Mean age 44 vs. 43 years 41% vs. 47% female Race not reported Using medication for LBP treatment 38% vs. 44% Pain, VAS: 6.2 vs. 5.9 Disability, ODI: 32.4 vs. 31.7
Prasad 2012	UK Single center	Age 18 to 45 years with onset of LBP symptoms within 6 months of study entry Excluded: Neurological deficits, cardio-respiratory disorder, pregnancy, weight >20% of ideal, MRI evidence of large sequestrated disc fragment	Randomized: 24 Analyzed: Varied by outcome) Attrition: 8% (2/24)	A. Inversion traction 3 times/week for 4 weeks + physiotherapy (n=13) B. Physiotherapy alone (n=11)	A vs. B Mean age 34 vs. 37 years 46% vs. 64% female Race not reported Pain, VAS: 3.2 vs. 2.8 Disability, ODI: 50 vs. 48 Disability, RMDQ: 12.5 vs. 10 Quality of life, SF36 physical function: 43.5 vs. 35.7

Appendix E60. Data Abstraction of Randomized Controlled Trials of Traction

Author, Year	Duration of Pain (acute, subacute, chronic)	Outcome Measures	Duration of Followup	Results (list results for acute, subacute and chronic separately)
Studies published since the APS and Cochrane reviews				
Diab 2012 and Diab 2013	Subacute/chronic: Mean duration not reported; entry criteria required duration ≥3 months	Pain: VAS (scale 0-10) Disability: ODI (scale 0-100)	6 months	A vs. B Pain, VAS at 10 weeks: 3.2 (SD 1.4) vs. 3.5 (SD 1.2); mean difference -0.30 (95% CI -0.88 to 0.28) Pain, VAS at 6 months: 2.6 (SD 1.1) vs. 3.5 (SD 1.2); mean difference -0.90 (95% CI -1.41 to -0.39) Disability, ODI at 10 weeks: 21.8 (SD 3.1) vs. 23.4 (SD 3.4); mean difference -1.60 (95% CI -3.05 to -0.15) Disability, ODI at 6 months: 23.8 (SD 2.7) vs. 27.1 (SD 3.0); mean difference -3.30 (95% CI -4.57 to -2.03)
Moustafa 2013	Subacute/chronic: Mean duration not reported; entry criteria required duration ≥3 months	Pain: VAS (scale 0-10) Disability: ODI (scale 0-100)	6 months	A vs. B Pain, VAS at 10 weeks: 2.3 (SD 1.6) vs. 3.5 (SD 1.04); mean difference -1.20 (95% CI -1.87 to -0.53) Pain, VAS at 6 months: 2.4 (SD 0.9) vs. 4.6 (SD 1.3); mean difference -2.20 (95% CI -2.79 to -1.62) Disability, ODI at 10 weeks: 19.8 (SD 3.7) vs. 23.7 (SD 3.8); mean difference -3.90 (95% CI -5.77 to -2.03) Disability, ODI at 6 months: 23.1 (SD 2.8) vs. 31.2 (SD 2.9); mean difference -8.10 (95% CI -9.60 to -6.60)
Prasad 2012	Acute/subacute: Mean duration not reported; entry criteria required <6 months duration of symptoms	Pain: VAS (scale 0-10) Disability: ODI (scale 0-100); RMDQ (scale 0-24; higher score=worse disability) Quality of life, SF-36 (scale 0-100)	6 weeks	A vs. B Number analyzed for each outcome varied Pain, VAS: 0.9 (n=12) vs. 3.0 (n=7); p not reported (inadequate data provided to calculate) Disability, ODI: 31 (n=8) vs. 54 (n=3); p=0.3 Disability, RMDQ: 7.5 (n=12) vs. 11 (n=7); p=0.55 Quality of life, SF-36 physical function mean change from baseline: 9.2 vs. 8.2; p=0.9; no significant difference between groups for other SF-36 measures including physical role, body pain, general health, vitality, social function, emotional role, mental health or change in health Need for surgery: 23% (3/13) vs. 82% (9/11); RR 0.28 (95% CI 0.10 to 0.79)

Appendix E60. Data Abstraction of Randomized Controlled Trials of Traction

Author, Year	Adverse Events Including Withdrawals	Funding Source	Quality Rating	Comments
Studies published since the APS and Cochrane reviews				
Diab 2012 and Diab 2013	Not reported	No external funding	Fair	
Moustafa 2013	Not reported	No external funding	Fair	
Prasad 2012	No serious adverse events in either group	Jacobson Charitable Trust	Poor	

Please see Appendix C. Included Studies for full study references.

Appendix E61. Data Abstraction of Randomized Controlled Trials of Taping

Author, Year	Country Number of Centers and Setting	Inclusion Criteria	Number Randomized, Analyzed Attrition	Intervention	Study Participants
Castro-Sanchez, 2012	Spain Single center	18 to 65 years of age, low back pain ≥3 months, RDQ ≥4, no flexion-relaxation in the lumbar muscles during trunk flexion Exclude: Clinical signs of radiculopathy, spinal stenosis, fibromyalgia, spondylolisthesis, previous surgery or Kinesio Tape therapy, corticosteroid treatment in past 2 weeks, central or peripheral nervous system disease	Randomized: 60 Analyzed: 60 Attrition: 0%	A: Kinesio Taping of lower back with 25% tension in star shape overlying point of maximum pain, applied for 7 days (n=30) B: Sham taping with single transverse strip above point of maximal pain, applied for 7 days (n=30)	A vs. B Mean age: 50 vs. 47 years Female: 70% vs. 66% Race: Not reported Pain intensity (0-10 VAS): 5.6 vs. 5.4 ODI (mean, 0-100): 28 vs. 29
Chen, 2012	Country unclear (author affiliations Taiwan and Australia) Single center	18 to 65 years of age, nonspecific low back pain >6 weeks Exclude: Spinal pathology, major trauma, systemic disease, cancer, osteoporosis, inflammatory disease, neurological deficit, pregnant, previous back surgery or waiting for surgery, active or pending legal proceedings due to low back pain, sensitivity to tape	Randomized: 43 Analyzed: 43 Attrition: 14% (19% vs. 9.1%)	A: Functional Fascial Taping with tension applied in direction that resulted in maximal pain reduction on trunk flexion, applied in 3 directions, reapplied daily for 2 weeks (n=21) B: Sham taping without tension (n=22) All patients given instruction for home trunk flexion exercises	A vs B Mean age: 46 vs. 40 years Female: 48% vs. 45% Average pain (mean, 0-100 VAS): 43 vs. 42 ODI (mean, 0-100): 31 vs. 24

Appendix E61. Data Abstraction of Randomized Controlled Trials of Taping

Author, Year	Duration of Pain (acute, subacute, chronic)	Duration of Followup	Results	Adverse Events Including Withdrawals	Funding Source	Quality Rating
Castro-Sanchez, 2012	All chronic, mean duration not reported	5 weeks (4 weeks after completion of therapy)	A vs. B Pain (mean difference in change from baseline, 0-10): -1.1 (95% CI -1.9 to -0.3) at 1 w, -1.0 (95% CI -1.7 to -0.2) at 5 w ODI (mean difference in change from baseline, 0-100): -4 (95% CI -6 to -2) at 1 w, 1 (95% CI -1 to 3) at 5 w RDQ (mean difference in change from baseline, 0-24): -1.2 (95% CI -2.0 to -0.4) at 1 w, 0.1 (95% CI -1.0 to 1.3) at 5 w	Not reported	Reports no funding support	Good
Chen, 2012	All >6 weeks, median 39 vs. 32 weeks	12 weeks (10 weeks after completion of therapy)	A vs. B Average pain (mean difference in change from baseline, 0-100): -7.6 +/- 6.2 (p=0.23) at 2 w, -0.73 +/- 5.9 (p=0.90) at 6 w, -3.6 +/-6.9 (p=0.60) at 12 w Worst pain (mean difference in change from baseline, 0-100): -17.3 +/- 7.2 (p=0.02) at 2 w, -11.3 +/- 8.1 (p=0.17) at 6 w, -5.8 +/- 7.6 (p=0.45) at 12 w ODI (mean difference in change from baseline, 0-100): -5.5 +/- 2.8 (p=0.05) at 2 w, -3.4 +/- 3.1 (p=0.28) at 6 w, -3.1 +/- 3.1 (p=0.33) at 12 w Average pain improved >20 points: 57% (12/21) vs. 36% (8/14) at 2 w, 57% (12/21) vs. 59% (13/22) at 6 w, 71% (15/21) vs. 59% (13/22) at 12 w Worst pain improved >20 points: 81% (17/21) vs. 41% (9/22) at 2 w, 67% (14/21) vs. 68% (15/22) at 6 w, 76% (16/21) vs. 77% (17/22) at 12 w ODI improved >10 points: 81% (17/21) vs. 41% (9/22) at 2 w, 71% (15/21) vs. 55% (12/22) at 6 w, 62% (13/21) vs. 50% (11/22) at 12 w	Not reported	Australian Centre for Research into Sports Injury and its Prevention	Fair

Appendix E61. Data Abstraction of Randomized Controlled Trials of Taping

Author, Year	Country Number of Centers and Setting	Inclusion Criteria	Number Randomized, Analyzed Attrition	Intervention	Study Participants
Kachanathu, 2014	Saudi Arabia Single center	nonspecific low back pain for >3 months	Randomized: 40 Analyzed: Unclear Attrition: Not reported	A: Kinesio Taping with two strips from origin of lumbar erector spinae to insertion with slight traction with patient flexing + exercise therapy (stretching and strengthening three sessions/week for 4 weeks) (n=20) B: Exercise therapy without Kinesio Taping (n=20)	Patient characteristics reported for whole sample Mean age: 35 years 25% female Race: Not reported Pain intensity (mean , 0-10): 6.2 vs. 6.1 RDQ (mean 0-24): 10.3 vs. 1.8
Paolini, 2011	Italy Single center	30 to 80 years of age, chronic (>12 weeks) low back pain, failed flexion relaxation during turn flexion Exclude: Clinical signs of radiculopathy, lumbar stenosis, spondylolisthesis, previous spinal surgery, corticosteroid treatment in past 2 weeks, central or peripheral nervous system diseases	Randomized: 39 Analyzed: 39 Attrition: Not reported	A: Kinesio Taping of lower back with 3 vertical strips placed with patient bending forward to create tension, applied for 3 days at time over 4 weeks (n=13) B: Exercise therapy, 30 minutes three times/week with stretching, relaxation, and active exercises (n=13) C: Kinesio Taping + exercise (n=13)	A vs B vs C Mean age: 63 vs. 63 vs. 62 years Female: 62% vs. 69% vs. 62% Race: Not reported Pain intensity (mean, 0-10 VAS): 7.1 vs. 7.6 vs. 7.6 RDQ (mean, 0-24): 10.3 vs. 9.9 vs. 9.5
Parreira, 2014	Brazil Single center	18 to 60 years of age with nonspecific chronic (≥ 3 months) low back pain Exclude: Contraindication to physical exercise (serious spinal pathology, nerve root compromise, serious cardiopulmonary conditions, pregnancy, contraindication to taping)	Randomized: 148 Analyzed: 148 Attrition: 0% at 12 weeks	A: Kinesio Taping over erector spinae muscles parallel to the spinous processes starting near the posterior superior iliac crest with 10% to 15% tension to create convolutions in the skin, applied for 48 hours, twice weekly for 4 weeks (n=74) B: Sham taping without tension (0% tension), applied for 48 hours, twice weekly for 4 weeks (n=74)	A vs B Mean age: 51 vs. 50 years 76% vs 80% female Race: Not reported Pain intensity (mean, 0-10 NRS): 7.0 vs. 6.8 RDQ (mean, 0-24): 11.5 vs. 10.4

Appendix E61. Data Abstraction of Randomized Controlled Trials of Taping

Author, Year	Duration of Pain (acute, subacute, chronic)	Duration of Followup	Results	Adverse Events Including Withdrawals	Funding Source	Quality Rating
Kachanathu, 2014	All chronic, mean duration not reported	4 weeks (at end of therapy)	A vs B Pain (mean, 0-10): 2.9 vs. 3.7 at 4 w (p=0.57) RDQ (mean, 0-24): 4.7 vs. 7.0 at 4 w (p=0.67)	Not reported	Not reported	Poor
Paolini, 2011	All chronic, duration <12 months in 85% vs. 62% Vs. 69%	4 weeks (at end of therapy)	A vs. B vs. C Pain (mean, 0-10): 3.1 vs. 3.5 vs. 3.7 at 3 w (p>0.05) RDQ (mean, 0-24): 9.5 vs. 5.4 vs. 7.3 at 3 w (p>0.05)	Not reported	Not reported	Fair
Parreira, 2014	Chronic: All chronic, mean duration 24 vs. 36 months	12 weeks (8 weeks after completion of therapy)	A vs B Pain (mean difference from baseline, 0-10 NRS): -0.4 (95% CI -1.3 to 0.4) at 4 w, -0.5 (95% CI -1.4 to 0.4) at 12 w RDQ (mean difference from baseline, 0-24): -0.3 (95% CI -1.9 to 1.3) at 4 w, 0.3 (95% CI -1.3 to 1.9) at 12 w Global Perceived Effect (mean difference from baseline, -5 to 5): 1.4 (95% CI 0.3 to 2.5) at 4 w, 0.4 (95% CI -0.7 to 1.5) at 12 w	Not reported	Fundacao de Amparao a Pesquia do Estado de Sao Paulo and Conselho Nacional de Desenvolvimento Cientifico e Tecnologico	Good

Please see Appendix C. Included Studies for full study references.

Appendix F1. Acetaminophen RCTs

Author, Year	Randomization	Concealed Treatment Allocation	Baseline Group Similarity	Patient Blinded	Care Provider Blinded	Outcome Assessor / Data Analyst Blinded	Cointerventions Avoided or Similar
Williams, 2014	Yes	Yes	Yes	Yes	Yes	Yes	Yes

Appendix F1. Acetaminophen RCTs

Author, Year	Compliance Acceptable in All Groups	Attrition Reported	Attrition Acceptable	Timing of Outcome Assessment in all Groups Similar	Intention-to-Treat Analysis	Is There a Registered or Published Protocol	Avoidance of Selective Outcomes Reporting	Quality Rating
Williams, 2014	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Good

Please see Appendix C. Included Studies for full study references.

Appendix F2. NSAIDs SRs

Study, Year	(1) 'A priori' design provided?	(2) Duplicate study selection and data extraction? a. Study selection b. Data extraction	(3) Comprehensive literature search performed?	(4) Status of publication used as an inclusion criteria?	(5) List of studies (included and excluded) provided?	(6) Characteristics of the included studies provided?
Roelofs, 2008	Yes	a. Yes b. Yes	Yes	Unclear	Yes	Yes

Appendix F2. NSAIDs SRs

Study, Year	(7) Scientific quality of included studies assessed and documented?	(8) Scientific quality of the included studies used appropriately in formulating conclusions?	(9) Methods used to synthesize the findings of studies appropriate?	(10) Likelihood of publication bias assessed?	(11) Conflict of interest stated? a) Systematic Review b) Individual Studies	Quality Rating
Roelofs, 2008	Yes	Yes	Yes	Yes	a. Yes b. No	Good

Please see Appendix C. Included Studies for full study references.

Appendix F3. NSAIDs RCTs

Author, Year	Randomization	Concealed Treatment Allocation	Baseline Group Similarity	Patient Blinded	Care Provider Blinded	Outcome Assessor / Data Analyst Blinded	Cointerventions Avoided or Similar
Studies published since the APS review							
Herrmann, 2009	Yes	Yes	Yes	Yes	Yes	Unclear	Yes
Majchrzycki, 2014	Yes	No	Yes	No	No	Unclear	Unclear
Shirado, 2010	Yes	No	Yes	No	No	Yes	Yes

Appendix F3. NSAIDs RCTs

Author, Year	Compliance Acceptable in All Groups	Attrition Reported	Attrition Acceptable	Timing of Outcome Assessment in all Groups Similar	Intention-to-Treat Analysis	Is There a Registered or Published Protocol	Avoidance of Selective Outcomes Reporting	Quality Rating
Studies published since the APS review								
Herrmann, 2009	Yes	Yes	Yes	Yes	Yes	No	Yes	Fair
Majchrzycki, 2014	Yes	Yes	Yes	Yes	Yes	No	Yes	Fair
Shirado, 2010	Yes	Yes	Yes	Yes	Yes	No	Yes	Good

Please see Appendix C. Included Studies for full study references.

Appendix F4. Opioids SRs

Author, Year	"A priori" design provided?	Duplicate study selection and data abstraction? a. Study selection b. Data abstraction	Comprehensive literature search performed?	Non-English language studies considered for inclusion?	Conducted searches for unpublished (gray) literature?	List of included studies provided?	List of excluded studies provided with reasons?	Characteristics of the included studies provided?
Chaparro, 2013	Yes	Yes to both	Yes	Yes	No	Yes	Yes- but only for 36 of 76 excluded articles	Yes

Appendix F4. Opioids SRs

Author, Year	Scientific quality of included studies: a. Assessed? b. Documented?	Sensitivity analyses or stratified analyses conducted according to study quality?	Study conclusions supported by the evidence? (Was study quality considered in the synthesis?)	Conflict of interest stated? a) Systematic Review b) Individual Studies	Multidisciplinary systematic review team?	Quality Rating
Chaparro, 2013	Yes to both	No, except for analysis 4.1, examining results of studies with "enhanced enrollment", meaning patients were enrolled only if they benefitted from opioids and tolerated side effects, then were randomized to opioid withdrawal.	Yes	a. Systematic review: Yes b. Individual studies: only for strong opioids	Yes	Good

Please see Appendix C. Included Studies for full study references.

Appendix F5. Opioids RCTs

Author, Year	Randomization	Concealed Treatment Allocation	Baseline Group Similarity	Patient Blinded	Care Provider Blinded	Outcome Assessor / Data Analyst Blinded	Cointerventions Avoided or Similar	Compliance Acceptable in all Groups
Cloutier, 2013	Yes	Yes	Yes	Yes	Yes	Yes	Unclear	Unclear
Hyup Lee 2013	Yes	Yes	Yes	Yes	Yes	Unclear	Yes	Yes
Rauck 2014	Unclear	Unclear	No; not sex	Yes	Yes	Unclear	Yes	Yes
Schiphorst Preuper 2014	Unclear	Yes	Yes	Yes	Yes	Yes	Unclear	Yes

Appendix F5. Opioids RCTs

Author, Year	Attrition Reported	Attrition Acceptable	Timing of Outcome Assessment in All Groups Similar	Intention-to-Treat Analysis	Is There A Registered or Published Protocol	Avoidance of Selective Outcomes Reporting	Quality Rating
Cloutier, 2013	Yes	No; <20%	Yes	Yes	Unclear	Unclear	Good
Hyup Lee 2013	Yes	No; 21%	Yes	Yes	Yes	Yes	Good
Rauck 2014	Yes	No; 39%	Yes	Yes	No	Yes	Poor
Schiphorst Preuper 2014	Yes	Yes	Yes	Yes	Yes	Yes	Fair

Please see Appendix C. Included Studies for full study references.

Appendix F6. Skeletal Muscle Relaxant RCTs

Author, Year	Randomization	Concealed Treatment Allocation	Baseline Group Similarity	Patient Blinded	Care Provider Blinded	Outcome Assessor / Data Analyst Blinded	Cointerventions Avoided or Similar
Pareek 2009	Unclear	Unclear	Yes	Yes	Unclear	Yes	Unclear
Ralph 2008	Unclear	Unclear	Yes	Yes	Unclear	Yes	Yes

Appendix F6. Skeletal Muscle Relaxant RCTs

Author, Year	Compliance Acceptable in all Groups	Attrition Reported	Attrition Acceptable	Timing of Outcome Assessment In All Groups Similar	Intention-to-Treat Analysis	Is There a Registered or Published Protocol	Avoidance of Selective Outcomes Reporting	Quality Rating
Pareek 2009	Yes	Yes	Yes	Yes	Yes	Unclear	Unclear	Fair
Ralph 2008	Yes	Yes	Yes	Yes	Yes	Unclear	Unclear	Fair

Please see Appendix C. Included Studies for full study references.

Appendix F7. Benzodiazepines RCTs

Author, Year	Randomization	Concealed Treatment Allocation	Baseline Group Similarity	Patient Blinded	Care Provider Blinded	Outcome Assessor / Data Analyst Blinded	Cointerventions Avoided or Similar	Compliance Acceptable in All Groups
Brotz, 2010	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

Appendix F7. Benzodiazepines RCTs

Author, Year	Attrition Reported	Attrition Acceptable	Timing of Outcome Assessment in all Groups Similar	Intention-to-Treat Analysis	Is There a Registered or Published Protocol	Avoidance of Selective Outcomes	Quality Rating
Brotz, 2010	Yes	Yes	Yes	Yes	Yes	Yes	Good

Please see Appendix C. Included Studies for full study references.

Appendix F8. Antidepressants SRs

Study, Year	(1) 'A priori' design provided?	(2) Duplicate study selection and data extraction? a. Study selection b. Data extraction	(3) Comprehensive literature search performed?	(4) Status of publication used as an inclusion criteria?	(5) List of studies (included and excluded) provided?	(6) Characteristics of the included studies provided?
Urquhart 2010	Yes	a. Yes b. No	Yes	Unclear	Yes	Yes

Appendix F8. Antidepressants SRs

Study, Year	(7) Scientific quality of included studies assessed and documented?	(8) Scientific quality of the included studies used appropriately in formulating conclusions?	(9) Methods used to synthesize the findings of studies appropriate?	(10) Likelihood of publication bias assessed?	(11) Conflict of interest stated? a) Systematic Review b) Individual Studies	Quality Rating
Urquhart 2010	Yes	Yes	Yes	Yes	a. Yes b. No	Good

Please see Appendix C. Included Studies for full study references.

Appendix F9. Antidepressants RCTs

Author, Year	Randomization	Concealed Treatment Allocation	Baseline Group Similarity	Patient Blinded	Care Provider Blinded	Outcome Assessor / Data Analyst Blinded	Cointerventions Avoided or Similar	Compliance Acceptable in All Groups
Farajirad 2013	Unclear	Unclear	Yes	Unclear	No	No	Unclear	Unclear
Mazza 2010	Unclear	Unclear	Yes	Unclear	Unclear	Unclear	Yes	Unclear
Skljarevski 2009	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Skljarevski 2010 (ref. #694)		Unclear	Unclear	Yes	Unclear	Yes	Yes	Yes
Skljarevski 2010 (ref. # 818)		Unclear	Unclear	Yes	Unclear	Yes	Yes	Yes

Appendix F9. Antidepressants RCTs

Author, Year	Attrition Reported	Attrition Acceptable	Timing of Outcome Assessment in all Groups Similar	Intention-to-Treat Analysis	Is There a Registered or Published Protocol	Avoidance of Selective Outcomes Reporting	Quality Rating
Farajirad 2013	No	Unclear	Unclear	Unclear	Unclear	Unclear	Poor
Mazza 2010	Yes	Yes	Yes	Yes	Unclear	Unclear	Fair
Skljarevski 2009	Yes	Yes	Yes	No	Unclear	Unclear	Good
Skljarevski 2010 (ref. #694)	Yes	Yes	Yes	No	Unclear	Unclear	Fair
Skljarevski 2010 (ref. # 818)	Yes	Yes	Yes	No	Unclear	Unclear	Fair

Please see Appendix C. Included Studies for full study references.

Appendix F10. Antiseizure RCTs

Author, Year	Randomization	Concealed Treatment Allocation	Baseline Group Similarity	Patient Blinded	Care Provider Blinded	Outcome Assessor / Data Analyst Blinded	Cointerventions Avoided or Similar	Compliance Acceptable in All Groups
Baron, 2010	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Baron, 2014	Unclear	Unclear	Yes	Yes	Yes	Unclear	Yes	Yes
Khoromi, 2005	Unclear	Yes	Unclear	Yes	Yes	Unclear	Unclear	Unclear
Markman, 2014`	Yes	Yes	Yes	Yes	Yes	Yes	Unclear	Yes
McCleane, 2001	Yes	Unclear	Yes	Yes	Yes	Unclear	Yes	Unclear
Muehlbacher, 2006	Yes	Unclear	Yes	Yes	Yes	Unclear	Yes	Unclear
Pota, 2012	Unclear	No	Yes	Yes	Unclear	Unclear	Unclear	Unclear
Romano, 2009	Unclear	Unclear	Unclear	Yes	Yes	Unclear	Yes	Unclear
Yaksi, 2007	Unclear	Unclear	Yes	Unclear	Unclear	Unclear	Yes	Unclear
Yildirim, 2003	Unclear	Unclear	Unclear	Yes	Unclear	Unclear	Yes	Unclear

Appendix F10. Antiseizure RCTs

Author, Year	Attrition Reported	Attrition Acceptable	Timing of Outcome Assessment in all Groups Similar	Intention-to-Treat Analysis	Is There a Registered or Published Protocol	Avoidance of Selective Outcomes Reporting	Quality Rating
Baron, 2010	Yes	Yes	Yes	Yes	Unclear	Yes	Fair
Baron, 2014	Yes	Yes	Yes	Yes	Unclear	Yes	Fair
Khoromi, 2005	Yes	No	Yes	No	Unclear	Yes	Poor
Markman, 2014`	Yes	Yes	Yes	Yes	Yes	Yes	Fair
McCleane, 2001	Yes	No	Yes	No	Unclear	Yes	Poor
Muehlbacher, 2006	Yes	Yes	Yes	Yes	Unclear	Yes	Fair
Pota, 2012	Yes	Yes	Yes	Yes	No	Yes	Fair
Romano, 2009	Yes	Yes	Yes	No	Unclear	Yes	Fair
Yaksi, 2007	No	Unclear	Yes	Unclear	Unclear	Yes	Poor
Yildirim, 2003	No	Unclear	Yes	Unclear	Unclear	Unclear	Poor

Please see Appendix C. Included Studies for full study references.

Appendix F11. Corticosteroids RCTs

Author, Year	Randomization	Concealed Treatment Allocation	Baseline Group Similarity	Patient Blinded	Care Provider Blinded	Outcome Assessor / Data Analyst Blinded	Cointerventions Avoided or Similar
Eskin, 2014	Yes	Unclear	Yes	Yes	Yes	Yes	Yes
Friedman, 2008	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Hedeboe, 1982	Unclear	Unclear	Unclear	Yes	Yes	Unclear	Yes
Holve, 2008	No (sequential allocation)	No	Unclear	Yes	Yes	Yes	Yes
Finckh, 2006	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Friedman, 2006	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Haimovic, 1986	Yes	Unclear	Unclear	Yes	Yes	Unclear	Unclear
Porsman, 1979	Unclear	Unclear	Unclear	Yes	Yes	Unclear	Yes

Appendix F11. Corticosteroids RCTs

Author, Year	Compliance Acceptable in All Groups	Attrition Reported	Attrition Acceptable	Timing of Outcome Assessment in all Groups Similar	Intention-to-Treat Analysis	Is There a Registered or Published Protocol	Avoidance of Selective Outcomes Reporting	Quality Rating
Eskin, 2014	Yes	Yes	Yes	Yes	No	Unclear	Yes	Fair
Friedman, 2008	Yes	Yes	Yes	Yes	Yes	Unclear	Yes	Good
Hedeboe, 1982	Unclear	No	Unclear	Yes	Yes	Unclear	Unclear	Fair
Holve, 2008	Unclear	Yes	Yes	Yes	Yes	Unclear	Yes	Poor
Finckh, 2006	Yes	Yes	Yes	Yes	Yes	Unclear	Yes	Good
Friedman, 2006	Yes	Yes	Yes	Yes	Yes	Unclear	Yes	Good
Haimovic, 1986	Unclear	Yes	Yes	Yes	Yes	Unclear	Unclear	Fair
Porsman, 1979	Unclear	Yes	Yes	Yes	No	Unclear	Unclear	Fair

Please see Appendix C. Included Studies for full study references.

Appendix F12. Exercise SRs

Author, Year	"A priori" design provided?	Duplicate study selection and data abstraction? a. Study selection b. Data abstraction	Comprehensive literature search performed?	Non-English language studies considered for inclusion?	Conducted searches for unpublished (gray) literature?	List of included studies provided?	List of excluded studies provided with reasons?	Characteristics of the included studies provided?
Oesch 2010	Yes	a. Yes; b. No	Yes , > 2 databases through Aug 2008; checked refs	No	Not stated	Yes	No	Yes
van Middelkoop 2010	Yes	a. Yes; b. Yes	Data bases through 2008 for CLBP only; unclear if additional sources	Cite Cochrane Back group strategy used - assume no restriction?	Cite Cochrane Back group strategy used - assume so?	Not explicitly; references provided	No	No

Appendix F12. Exercise SRs

Author, Year	Scientific quality of included studies: a. Assessed? b. Documented?	Sensitivity analyses or stratified analyses conducted according to study quality?	Study conclusions supported by the evidence? (Was study quality considered in the synthesis?)	Conflict of interest stated? a) Systematic Review b) Individual Studies	Multidisciplinary systematic review team?	Quality Rating
Oesch 2010	a. According to Juni b. Not by study	metaregresion-NS Effect of specific exercise characteristics; sensitivity by study quality; funnel plot	Yes	a. Funding source stated b. No	Yes	Fair
van Middelkoop 2010	a. Yes b. Yes	No	Yes	a. No b. No	Unclear	Fair

Please see Appendix C. Included Studies for full study references.

Appendix F13. Exercise RCTs

Author, Year	Randomization	Concealed Treatment Allocation	Baseline Group Similarity	Patient Blinded	Care Provider Blinded	Outcome Assessor / Data Analyst Blinded	Cointerventions Avoided or Similar	Compliance Acceptable in All Groups
Albaladejo 2010	Yes	Yes	Yes	No	No	Yes	Unclear	Unclear
Albert, 2012	Yes	No	Yes	No	No	Yes	Unclear	Unclear
Bronfort 2011	Yes	Yes	Yes	No	No	Yes	Unclear	Yes
George, 2008B	Yes	No	No	No	No	Yes	Unclear	Unclear
Hagen 2010	Yes	No	Yes	No	No	Yes	Unclear	Unclear
Hartvigsen 2010	Unclear	Yes	Yes	No	No	Unclear	Unclear	Unclear
Helmhout 2008	Yes	Unclear	No	No	No	Unclear	Unclear	Unclear
Henchoz 2010	Unclear	Unclear	Yes	No	No	No	Unclear	No
Hofstee 2002	Yes	No	No	No	No	No	No	Unclear
Hurley 2015	Yes	Yes	Yes	No	No	Yes	Unclear	No
Jensen 2012	Yes	Yes	Yes	No	No	Yes	Unclear	Yes
Kell 2011	Unclear	Unclear	Yes	No	No	Unclear	Unclear	Unclear
Little 2008	Yes	Yes	Yes	No	No	Yes	Unclear	Yes
Machado 2010	Yes	Yes	Yes	No	No	Yes	Unclear	Yes
Pengel 2007	Yes	Yes	Yes	Unclear/ sham	No	Yes	No	Unclear

Appendix F13. Exercise RCTs

Author, Year	Attrition Reported	Attrition Acceptable	Timing of Outcome Assessment in All Groups Similar	Intention-to-Treat Analysis	Is There a Registered or Published Protocol	Avoidance of Selective Outcomes Reporting	Quality Rating
Albaladejo 2010	Yes	Yes	Yes	Yes	Yes	Yes	Fair (but results reporting poor)
Albert, 2012	Yes	Yes	Yes	Yes	Yes	Unclear	Fair
Bronfort 2011	Yes	Yes	Yes	Yes	Yes	Yes	Good
George, 2008B	Yes	No	Yes	Yes	Yes	Unclear	High/poor
Hagen 2010	Yes	Yes	Yes	Yes	No	Unclear	Fair
Hartvigsen 2010	Yes	Yes	Yes	Yes	Yes	Yes	Fair
Helmhout 2008	Yes	Yes	Yes	Yes	Yes	Unclear	Poor
Henchoz 2010	Yes	Yes	Yes	Yes	No	Yes	Poor
Hofstee 2002	Yes	Yes	Yes	Yes	No	Unclear	High/poor
Hurley 2015	Yes	No	Yes	Yes	Yes	Yes	Fair
Jensen 2012	Yes	Yes	Yes	Yes	Yes	Yes	Good
Kell 2011	No	Unclear	Yes	Unclear	No	Yes	Poor
Little 2008	Yes	Yes	Yes	Unclear	Yes	Yes	Good
Machado 2010	Yes	Yes	Yes	Yes	Yes	Unclear	Fair
Pengel 2007	Yes	Yes	Yes	Yes	Yes	Unclear	Fair

Please see Appendix C. Included Studies for full study references.

Appendix F14. MCE SRs

Author, Year	"A priori" design provided?	Duplicate study selection and data abstraction? a. Study selection b. Data abstraction	Comprehensive literature search performed?	Non-English language studies considered for inclusion?	Conducted searches for unpublished (gray) literature?	List of included studies provided?	List of excluded studies provided with reasons?
Bystrom 2013	yes	a. Yes; b. no	> 2 databases through Oct 2011;no mention of "plus" sources	no	not stated	yes	no

Appendix F14. MCE SRs

Author, Year	Characteristics of the included studies provided?	Scientific quality of included studies: a. Assessed? b. Documented?	Sensitivity analyses or stratified analyses conducted according to study quality?	Study conclusions supported by the evidence? (Was study quality considered in the synthesis?)	Conflict of interest stated? a) Systematic Review b) Individual Studies	Multidisciplinary systematic review team?	Quality Rating
Bystrom 2013	yes	a. 10-point PEDro scale b. marginally - score out of 10 provided; areas of methodological concern for studies not described	no; no information on heterogeneity provided;	yes	a. Systematic review: Yes, however 1 author is also author of one of the included trials b. Individual studies: No	unclear	fair

Please see Appendix C. Included Studies for full study references.

Appendix F15. MCE RCTs

Author, Year	Randomization	Concealed Treatment Allocation	Baseline Group Similarity	Patient Blinded	Care Provider Blinded	Outcome Assessor / Data Analyst Blinded	Cointerventions Avoided or Similar	Compliance Acceptable in All Groups
Inani 2013	Yes	No	Yes	No	No	No	Unclear	Unclear
Macedo 2012	Yes	Yes	Yes	No	No	Yes	Unclear	Unclear

Appendix F15. MCE RCTs

Author, Year	Attrition Reported	Attrition Acceptable	Timing of Outcome Assessment in all Groups Similar	Intention-to-Treat Analysis	Is There a Registered or Published Protocol	Avoidance of Selective Outcomes Reporting	Quality Rating
Inani 2013	Yes	Yes	Yes	Yes	No	Unclear	poor
Macedo 2012	Yes	Yes	Yes	Yes	Yes	Unclear	fair

Please see Appendix C. Included Studies for full study references.

Appendix F16. Pilates SRs

Author, Year	"A priori" design provided?	Duplicate study selection and data abstraction? a. Study selection b. Data abstraction	Comprehensive literature search performed?	Non-English language studies considered for inclusion?	Conducted searches for unpublished (gray) literature?	List of included studies provided?	List of excluded studies provided with reasons?	Characteristics of the included studies provided?
Wells 2014	Yes	a. Yes; b. No	Yes, >2 databases including CINAHL, Cochrane Library, Scopus	no	Yes (Proquest - dissertations and theses; Nursing and Allied Health Source; hand search of bibliographies	Yes	no	yes

Appendix F16. Pilates SRs

Author, Year	Scientific quality of included studies: a. Assessed? b. Documented?	Sensitivity analyses or stratified analyses conducted according to study quality?	Study conclusions supported by the evidence? (Was study quality considered in the synthesis?)	Conflict of interest stated? a) Systematic Review b) Individual Studies	Multidisciplinary systematic review team?	Quality Rating
Wells 2014	Yes: Modified Guidelines for use of the McMasters Critical Appraisal Form for Quantitative Studies	No; no metaanalysis done; quality rating	No ; Study quality (high vs. low quality) described w/results; conclusions regarding pain short term - may be over stated;	a. yes b. no	unclear	moderate

Please see Appendix C. Included Studies for full study references.

Appendix F17. Tai Chi RCTs

Author, Year	Randomization	Concealed Treatment Allocation	Baseline Group Similarity	Patient Blinded	Care Provider Blinded	Outcome Assessor / Data Analyst Blinded	Cointerventions Avoided or Similar
Hall 2011	Yes	Yes	Yes	No	No	No	Unclear
Weifen 2013	Unclear	Unclear	Yes	No	No	Yes	Unclear

Appendix F17. Tai Chi RCTs

Author, Year	Compliance Acceptable in All Groups	Attrition Reported	Attrition Acceptable	Timing of Outcome Assessment in All Groups Similar	Intention-to-Treat Analysis	Is There a Registered or Published Protocol	Avoidance of Selective Outcomes Reporting	Quality Rating
Hall 2011	Yes	Yes	Yes	Yes	Yes	No	Yes	Fair
Weifen 2013	Yes	No	Unclear	Yes	Unclear	No	Yes	Poor

Please see Appendix C. Included Studies for full study references.

Appendix F18. Yoga SRs

Author, Year	"A priori" design provided?	Duplicate study selection and data abstraction? a. Study selection b. Data abstraction	Comprehensive literature search performed?	Non-English language studies considered for inclusion?	Conducted searches for unpublished (gray) literature?	List of included studies provided?	List of excluded studies provided with reasons?	Characteristics of the included studies provided?
Cramer 2013	Yes	a. Not stated explicitly; Stated used PRISMA and Cochrane methods b. Yes	January 2012: Medline, EMBASE, the Cochrane Library, PsycINFO, and CAMBASE	Yes	No	Yes	Yes - full text; reason with citation	Yes

Appendix F18. Yoga SRs

Author, Year	Scientific quality of included studies: a. Assessed? b. Documented?	Sensitivity analyses or stratified analyses conducted according to study quality?	Study conclusions supported by the evidence? (Was study quality considered in the synthesis?)	Conflict of interest stated? a) Systematic Review b) Individual Studies	Multidisciplinary systematic review team?	Quality Rating
Cramer 2013	a. 2009 Updated Method Guidelines for Systematic Reviews in the Cochrane Back Review Group b. Yes	Yes; high vs low ROB; if heterogeneity	Study quality considered; Conclusions regarding pain, disability are supported; HRQOL conclusions - seem to be downgraded more (short term) than rating scheme might suggest? Limited info on adverse events available, but conclude that Yoga not associated w/serious adverse events	a. Systematic review: Yes b. Individual studies: No		Good

Please see Appendix C. Included Studies for full study references.

Appendix F19. Quality Assessment of Randomized Controlled Trials of Yoga

Author, Year	Randomization	Concealed Treatment Allocation	Baseline Group Similarity	Patient Blinded	Care Provider Blinded	Outcome Assessor / Data Analyst Blinded	Cointerventions Avoided or Similar
Nambi 2014	Yes	Unclear	Yes	No	Unclear	Unclear	Unclear
Saper 2013	Yes	Unclear	No (But adjusted estimates for baseline differences were essentially the same as crude estimates)	No	Unclear	Yes	Yes use of other treatments overall: 53% (26/47) vs. 61% (28/44); similar % for massage, PH, acupuncture, chiropractic, epidural injections

Appendix F19. Quality Assessment of Randomized Controlled Trials of Yoga

Author, Year	Compliance Acceptable in All Groups	Attrition Reported	Attrition Acceptable	Timing of Outcome Assessment in All Groups Similar	Intention-to-Treat Analysis	Is There a Registered or Published Protocol	Avoidance of Selective Outcomes Reporting	Quality Rating
Nambi 2014	Unclear	Yes	Yes	Yes	Yes	No	unclear	Poor
Saper 2013	No; attendance: 65% for once weekly class, 44% for twice weekly classes	Yes	Yes	Yes	Yes	Yes	Yes	Fair

Please see Appendix C. Included Studies for full study references.

Appendix F20. Psych Therapies SRs

Author, Year	"A priori" design provided?	Duplicate study selection and data abstraction? a. Study selection b. Data abstraction	Comprehensive literature search performed?	Non-English language studies considered for inclusion?	Conducted searches for unpublished (gray) literature?	List of included studies provided?	List of excluded studies provided with reasons?
Henschke (Cochrane) 2011	Yes	a. Yes b. Yes	Yes	Yes	Unclear	Yes	Yes

Appendix F20. Psych Therapies SRs

Author, Year	Characteristics of the included studies provided?	Scientific quality of included studies: a. Assessed? b. Documented?	Sensitivity analyses or stratified analyses conducted according to study quality?	Study conclusions supported by the evidence? (Was study quality considered in the synthesis?)	Conflict of interest stated? a) Systematic Review b) Individual Studies	Multidisciplinary systematic review team?	Quality Rating
Henschke (Cochrane) 2011	Yes	a. Yes b. Yes	No	Yes (yes)	a. Yes b. No	Yes	High

Please see Appendix C. Included Studies for full study references.

Appendix F21. Psych Therapies RCTs

Author, Year	Randomization	Concealed Treatment Allocation	Baseline Group Similarity	Patient Blinded	Care Provider Blinded	Outcome Assessor / Data Analyst Blinded	Cointerventions Avoided or Similar
Lamb 2010/2012	Yes	Yes	Yes	No	No (but blinding not possible for these interventions)	Yes	No (control group free to seek any additional care on their own; additional treatments received not reported)
Morone 2008	Yes	Yes	Yes	No	No (but blinding not possible for these interventions)	Unclear	Yes
Morone 2009	Yes	Yes	No (age)	No	No (but blinding not possible for these interventions)	Yes	Yes
Siemonsma 2013	Yes	Yes	Yes	No	No (but blinding not possible for these interventions)	Yes	Yes
Vong 2011	Yes	Unclear	Yes	Yes (patients told they would receive one of two types of conventional patient treatment but did not know anything about motivational enhancement therapy)	No (but blinding not possible for these interventions)	Yes (outcomes patient reported)	yes

Appendix F21. Psych Therapies RCTs

Author, Year	Compliance Acceptable in All Groups	Attrition Reported	Attrition Acceptable	Timing of Outcome Assessment in All Groups Similar	Intention-to-Treat Analysis	Is There a Registered or Published Protocol	Avoidance of Selective Outcomes Reporting	Quality Rating
Lamb 2010/2012	No Intervention group: 63% (294/468) Control group: 100% (233/233)	Yes	Yes (85% in both groups)	Yes	No	Yes	Yes	Fair
Morone 2008	No Intervention group: 68% Control group: 94%	Yes	No (68% (25/37))	Yes	No	No	Yes	Fair
Morone 2009	No Intervention group: 80% Control group: 95%	Yes	Yes (88%)	Yes	No	No	Yes	Fair
Siemonsma 2013	No Intervention group: 81.7% Control group (waiting list, no interventions permitted): Unclear	Yes	Yes (89% was lowest f/u reported (for activity-specific pain, 139/156)	Yes	No (Their fig 1 makes it look like all pts randomized were included in the primary analysis but the paragraph under "Primary Outcome" contradicts this.	Yes	Yes	Fair
Vong 2011	No Intervention group: 62% Control group: 63% (% of patients who participated fully)	yes	yes (86%)	yes	No (they said they used ITT but 12 patients who were randomized did not receive treatment and were excluded from all analyses)	No	yes	Fair

Please see Appendix C. Included Studies for full study references.

Appendix F22. Multidisciplinary Rehabilitation SRs

Author, Year	"A priori" design provided?	Duplicate study selection and data abstraction? a. Study selection b. Data abstraction	Comprehensive literature search performed?	Non-English language studies considered for	Conducted searches for unpublished (gray) literature?	List of included studies provided?	List of excluded studies provided with reasons?	Characteristics of the included studies provided?
Kamper, 2014	Yes	a. Yes b. Yes	Yes	Y es	No	Yes	No	Yes

Appendix F22. Multidisciplinary Rehabilitation SRs

Author, Year	Scientific quality of included studies: a. Assessed? b. Documented?	Sensitivity analyses or stratified analyses conducted according to study quality?	Study conclusions supported by the evidence? (Was study quality considered in the synthesis?)	Conflict of interest stated? a) Systematic Review b) Individual Studies	Multidisciplinary systematic review team?	Quality Rating
Kamper, 2014	a. Yes b. Yes	Yes	Yes	a. Yes b. No	Yes	High

Please see Appendix C. Included Studies for full study references.

Appendix F23. Multidisciplinary Rehabilitation RCTs

Author, Year	Randomization	Concealed Treatment Allocation	Baseline Group Similarity	Patient Blinded	Care Provider Blinded	Outcome Assessor / Data Analyst Blinded	Cointerventions Avoided or Similar
Eisenberg 2012	Yes	Unclear	Yes	No	No	Unclear	NA
Gatchel 2003	Yes	Unclear	Unclear	No	No	Unclear	NA

Appendix F23. Multidisciplinary Rehabilitation RCTs

Author, Year	Compliance Acceptable in All Groups	Attrition Reported	Attrition Acceptable	Timing of Outcome Assessment in All Groups Similar	Intention-to-Treat Analysis	Is There a Registered or Published Protocol	Avoidance of Selective Outcomes Reporting	Quality Rating
Eisenberg 2012	Yes	Yes	Yes	Yes	Yes	No	Unclear	High quality
Gatchel 2003	Yes	No	NA	Yes	Unclear	Yes	Unclear	Fair

Please see Appendix C. Included Studies for full study references.

Appendix F24. Acupuncture SRs

Author, Year	"A priori" design provided?	Duplicate study selection and data abstraction? a. Study selection b. Data abstraction	Comprehensive literature search performed?	Non-English language studies considered for inclusion?	Conducted searches for unpublished (gray) literature?	List of included studies provided?	List of excluded studies provided with reasons?	Characteristics of the included studies provided?
Lee 2013	Unclear	a. Yes b. Yes	Yes	Yes	Yes	Yes	No	Yes
Lam 2013	Unclear	a. Yes b. Yes	Yes	Yes	No	Yes	No	Yes

Appendix F24. Acupuncture SRs

Author, Year	Scientific quality of included studies: a. Assessed? b. Documented?	Sensitivity analyses or stratified analyses conducted according to study quality?	Study conclusions supported by the evidence? (Was study quality considered in the synthesis?)	Conflict of interest stated? a) Systematic Review b) Individual Studies	Multidisciplinary systematic review team?	Quality Rating
Lee 2013	a. Yes b. Yes	Yes	Yes	a. Yes b. No	No	Fair
Lam 2013	a. Yes b. Yes	No	Unclear	a. Yes b. No	No	Fair

Please see Appendix C. Included Studies for full study references.

Appendix F25. Acupuncture RCTs

Author, Year	Randomization adequate?	Allocation concealment adequate?	Groups similar at baseline?	Eligibility criteria specified?	Patients masked?	Care provider masked?
Hasagawa, 2014	Yes	Yes	Yes	Yes	Yes	No
Vas, 2012	Yes	Yes	Yes	Yes	Yes (for acupuncture and sham groups only)	No
Cho, 2013	Yes	Yes	Yes	Yes	Yes	No

Appendix F25. Acupuncture RCTs

Author, Year	Outcomes assessors masked?	Attrition and withdrawals reported?	Attrition acceptable and comparable?	Analyze people in the groups in which they were randomized	Primary outcome specified and reported?	Other issues	Quality Rating
Hasagawa, 2014	Yes	Yes	Yes	Yes	Yes	None	Good
Vas, 2012	Yes	Yes	Yes	Yes	Yes	None	Good
Cho, 2013	Yes	Yes	Yes	Yes	Yes	None	Good

Please see Appendix C. Included Studies for full study references.

Appendix F26. Massage SRs

Author, Year	"A priori" design provided?	Duplicate study selection and data abstraction? a. Study selection b. Data abstraction	Comprehensive literature search performed?	Non-English language studies considered for inclusion?	Conducted searches for unpublished (gray) literature?	List of included studies provided?	List of excluded studies provided with reasons?
Furlan 2010	Yes	a. Yes b. Yes	Yes	Yes	Yes	Yes	Yes

Appendix F26. Massage SRs

Author, Year	Characteristics of the included studies provided?	Scientific quality of included studies: a. Assessed? b. Documented?	Sensitivity analyses or stratified analyses conducted according to study quality?	Study conclusions supported by the evidence? (Was study quality considered in the synthesis?)	Conflict of interest stated? a) Systematic Review b) Individual Studies	Multidisciplinary systematic review team?	Quality Rating
Furlan 2010	Yes	a. Yes b. Yes	Yes	Yes	a. Yes b. No	Yes	Good

Please see Appendix C. Included Studies for full study references.

Appendix F27. Massage RCTs

Author, Year	Randomization adequate?	Allocation concealment adequate?	Groups similar at baseline?	Eligibility criteria specified?	Outcome assessors masked?	Care provider masked?
Cherkin, 2011	Yes	Yes	Yes	Yes	Yes - for the two massage groups only	No
Sritooma, 2014	Yes	Unclear	Yes	Yes	No	No
Romanowski, 2012	Unclear	Unclear	Yes	Yes	Yes	No
Kong, 2012	Yes	Yes	Yes	Yes	Yes	No

Appendix F27. Massage RCTs

Author, Year	Patient masked?	Attrition and withdrawals reported?	Attrition acceptable and comparable?	Analyze people in the groups in which they were randomized	Primary outcome specified and reported?	Other issues	Quality Rating
Cherkin, 2011	Yes	Yes	Yes	Yes	Yes	None	Good
Sritooma, 2014	No - not described	Yes	Yes	Yes	Yes	None	Fair
Romanowski, 2012	Yes	Yes	Yes	Yes	Yes	None	Poor
Kong, 2012	Yes	Yes	Yes	Yes	Yes	None	Good

Please see Appendix C. Included Studies for full study references.

Appendix F28. Spinal Manipulation SRs

Author, Year	"A priori" design provided?	Duplicate study selection and data abstraction? a. Study selection b. Data abstraction	Comprehensive literature search performed?	Non-English language studies considered for inclusion?	Conducted searches for unpublished (gray) literature?	List of included studies provided?	List of excluded studies provided with reasons?
Rubinstein 2011	Yes	a. Yes b. Yes	Yes	Yes	Yes	Yes	Yes
Rubinstein 2012	Yes	a. Yes b. Yes	Yes	Unclear	Yes, but excluded from analysis	Yes	Yes

Appendix F28. Spinal Manipulation SRs

Author, Year	Characteristics of the included studies provided?	Scientific quality of included studies: a. Assessed? b. Documented?	Sensitivity analyses or stratified analyses conducted according to study quality?	Study conclusions supported by the evidence? (Was study quality considered in the synthesis?)	Conflict of interest stated? a) Systematic Review b) Individual Studies	Multidisciplinary systematic review team?	Quality Rating
Rubinstein 2011	Yes	a. Yes b. Yes	Yes	Yes	a. Yes b. Yes	Yes	Good
Rubinstein 2012	Yes	a. Yes b. Yes	Yes	Yes	a. Yes b. Yes	Yes	Good

Please see Appendix C. Included Studies for full study references.

Appendix F29. Spinal Manipulation RCTs

Author, Year	Randomization adequate?	Allocation concealment adequate?	Groups similar at baseline?	Eligibility criteria specified?	Patient masked?	Care provider masked?
Balthazard, 2012	Yes	Unclear	Yes - although pain slightly higher in sham group (53 vs 62) but not SS	Yes	No	No
Bicahlo, 2010	Yes	Unclear	Yes	Yes	No	No
Cecchi, 2010	Yes	Unclear	No - sick leave higher in back school group compared to other groups	Yes	No	No
De Oliviera, 2013	Yes	Yes	Yes	Yes	Yes	No
Goertz, 2013	Yes	Yes	Yes	Yes	No	No
Haas, 2014	Yes	Yes	Yes	Yes	No	No
Hawk, 2005	Yes	Unclear	Yes	Yes	No - attempted, but wasn't successful	No
Mathews, 1987	Unclear	Unclear	Yes	Yes	No	No
Paatelma, 2008	Yes	Yes	Yes	Yes	No	No
Petersen, 2011	Yes	Yes	Yes	Yes	No	No
Senna, 2011	Yes	Yes	Yes	Yes	Yes	No
Von Heymann, 2013	Yes	Yes	Yes	Yes	Yes	No

Appendix F29. Spinal Manipulation RCTs

Author, Year	Outcomes assessor masked?	Attrition and withdrawals reported?	Attrition acceptable and comparable?	Analyze people in the groups in which they were randomized	Primary outcome specified and reported?	Other issues	Quality Rating
Balthazard, 2012	Unclear	Yes	Yes	Yes	Yes	None	Fair
Bicahlo, 2010	Unclear	Yes	Yes	Yes	Yes	Incomplete reporting of outcomes (function)	Fair
Cecchi, 2010	Unclear	Yes	Yes	Yes	Yes	None	Fair
De Oliviera, 2013	Yes	Yes	Yes	Yes	Yes	None	Good
Goertz, 2013	Yes	Yes	No - low follow up rate in the SMC group	Yes	Yes	None	Fair
Haas, 2014	Yes	Yes	Yes	Yes	Yes	None	Good
Hawk, 2005	Yes	Yes	Yes	Yes	Yes	None	Fair
Mathews, 1987	Yes	Yes	Yes	Yes	No	None	Poor
Paatelma, 2008	Yes	Yes	No - high dropout rate	Yes	Yes	None	Fair
Petersen, 2011	Yes	Yes	Yes	Yes	Yes	None	Good
Senna, 2011	Yes	Yes	No - low follow up rate in sham SMT group	Yes	Yes	None	Fair
Von Heymann, 2013	Yes	Yes	No - low follow up rate	Yes	Yes	Unclear intervention (? Single treatment?), small sample size with high dropout rate	Fair

Please see Appendix C. Included Studies for full study references.

Appendix F30. Ultrasound SRs

Author, Year	"A priori" design provided?	Duplicate study selection and data abstraction? a. Study selection b. Data abstraction	Comprehensive literature search performed?	Non-English language studies considered for inclusion?	Conducted searches for unpublished (gray) literature?	List of included studies provided?	List of excluded studies provided with reasons?	Characteristics of the included studies provided?
Ebadi, 2014	Yes	Yes/Yes	Yes	Yes	Yes	Yes	Yes	Yes

Appendix F30. Ultrasound SRs

Author, Year	Scientific quality of included studies: a. Assessed? b. Documented?	Sensitivity analyses or stratified analyses conducted according to study quality?	Study conclusions supported by the evidence? (Was study quality considered in the synthesis?)	Conflict of interest stated? a) Systematic Review b) Individual Studies	Multidisciplinary systematic review team?	Quality Rating
Ebadi, 2014	Yes	Yes (considered in SOE analyses)	Yes	Yes/No	Yes	Good

Please see Appendix C. Included Studies for full study references.

Appendix F31. Ultrasound RCTs

Author, Year	Randomization	Concealed Treatment Allocation	Baseline Group Similarity	Patient Blinded	Care Provider Blinded	Outcome Assessor / Data Analyst Blinded	Cointerventions Avoided or Similar
Studies included in the APS review							
Ansari, 2006	Unclear	Unclear	No	Yes	No	Unclear	Unclear
Nwuga, 1983	No	No	Unclear	Yes	Unclear	Yes	Unclear
Roman, 1960	Unclear	Unclear	Unclear	Yes	Unclear	Unclear	Unclear
Studies published since the APS review							
Ebadi, 2012	Yes	Unclear	Unclear	Yes	No	Unclear	Unclear
Licciardone, 2013	Yes	Yes	Yes	Yes	Unclear	Unclear	Yes
Unlu, 2008	Unclear	Unclear	Yes	No	No	Unclear	Unclear

Appendix F31. Ultrasound RCTs

	Compliance Acceptable in all Groups	Attrition Reported	Attrition Acceptable	Timing of Outcome Assessment in all Groups Similar	Intention-to-Treat Analysis	Is There a Registered or Published Protocol	Avoidance of Selective Outcomes Reporting	Quality (Cochrane Back Group)
Studies included in the APS review								
Ansari, 2006	Unclear	Yes	No	Yes	No	Unclear	Unclear	Poor
Nwuga, 1983	Unclear	Unclear	Unclear	Yes	Unclear	Unclear	Unclear	Poor
Roman, 1960	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear	Poor
Studies published since the APS review								
Ebadi, 2012	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Fair
Licciardone, 2013	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Good
Unlu, 2008	Unclear	No	Unclear	Yes	Unclear	Unclear	Unclear	Poor

Please see Appendix C. Included Studies for full study references.

Appendix F32. TENS SRs

Author, Year	"A priori" design provided?	Duplicate study selection and data abstraction? a. Study selection b. Data abstraction	Comprehensive literature search performed?	Non-English language studies considered for inclusion?	Conducted searches for unpublished (gray) literature?	List of included studies provided?	List of excluded studies provided with reasons?	Characteristics of the included studies provided?
van Middelkoop 2011	Yes	A. Yes B. Yes	Yes	Yes	Unclear	Yes	No	Yes

Appendix F32. TENS SRs

Author, Year	Scientific quality of included studies: a. Assessed? b. Documented?	Sensitivity analyses or stratified analyses conducted according to study quality?	Study conclusions supported by the evidence? (Was study quality considered in the synthesis?)	Conflict of interest stated? a) Systematic Review b) Individual Studies	Multidisciplinary systematic review team?	Quality Rating
van Middelkoop 2011	a. Yes b. Yes	Unclear	Yes	a. Yes b. Yes	Unclear	Good

Please see Appendix C. Included Studies for full study references.

Appendix F33. TENS RCTs

Author, Year	Randomization	Concealed Treatment Allocation	Baseline Group Similarity	Patient Blinded	Care Provider Blinded	Outcome Assessor / Data Analyst Blinded	Cointerventions Avoided or Similar	Compliance Acceptable in All Groups
Buchmuller 2012	Yes	Yes	Yes	Yes	No	No	Yes	Yes
Facci 2011	Yes	Yes	No; significant difference between TENS and control in pain intensity at baseline (p=0.009)	Yes	Unclear	Yes	Yes	Yes
Shimoji 2007	Unclear	Unclear	Yes	Yes	Unclear	Yes	Yes	Yes

Appendix F33. TENS RCTs

Author, Year	Attrition Reported	Attrition Acceptable	Timing of Outcome Assessment in all Groups Similar	Intention-to-Treat Analysis	Is There a Registered or Published Protocol	Avoidance of Selective Outcomes Reporting	Quality Rating
Buchmuller 2012	Yes	No	Yes	Unclear	Unclear	Unclear	Fair
Facci 2011	Yes	Yes	Yes	Yes	Unclear	Unclear	Good
Shimoji 2007	No	Unclear	Yes	Unclear	Unclear	Unclear	Fair

Please see Appendix C. Included Studies for full study references.

Appendix F34. EMS RCTs

Author, Year	Randomization	Concealed Treatment Allocation	Baseline Group Similarity	Patient Blinded	Care Provider Blinded	Outcome Assessor / Data Analyst Blinded	Cointerventions Avoided or Similar	Compliance Acceptable in all Groups
Durmus, 2009	Unclear	Unclear	Yes	No	No	Unclear	Unclear	Unclear
Durmus, 2010	Unclear	Unclear	Yes	No	No	Unclear	Unclear	Unclear
Glaser, 2001	Yes	Unclear	Yes	Yes	Yes	Unclear	Unclear	Unclear
Moore, 1997	Unclear	Unclear	Unclear	Yes	Unclear	Unclear	Unclear	Unclear
Pope, 1994	Yes	Unclear	Unclear	No	No	Yes	Unclear	No

Appendix F34. EMS RCTs

Author, Year	Attrition Reported	Attrition Acceptable	Timing of Outcome Assessment in all Groups Similar	Intention-to-Treat Analysis	Is There a Registered or Published Protocol	Avoidance of Selective Outcomes Reporting	Quality (Cochrane Back Group)	Comments
Durmus, 2009	No	Unclear	Yes	Unclear	Unclear	Yes	Poor	Some outcomes assessed as means and others as medians, no explanation provided
Durmus, 2010	Yes	Yes	Yes	No	Unclear	Yes	Poor	Some outcomes assessed as means and others as medians, no explanation provided
Glaser, 2001	Yes	No	Yes	No	Unclear	Yes	Poor	Very high loss to followup
Moore, 1997	Yes	Yes	Yes	No	Unclear	Yes	Poor	Crossover design, results of first intervention not reported and carryover effects not assessed
Pope, 1994	Yes	Yes	Yes	Unclear	Yes	Yes	Fair	

Please see Appendix C. Included Studies for full study references.

Appendix F35. PENS RCTs

Author, Year	Randomization	Concealed Treatment Allocation	Baseline Group Similarity	Patient Blinded	Care Provider Blinded	Outcome Assessor / Data Analyst Blinded	Cointerventions Avoided or Similar
Hamza, 1999	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear
Pérez-Palomares, 2010	Yes	Unclear	Unclear	No	No	Yes	Unclear

Appendix F35. PENS RCTs

Author, Year	Compliance Acceptable in all Groups	Attrition Reported	Attrition Acceptable	Timing of Outcome Assessment in all Groups Similar	Intention-to-Treat Analysis	Is There a Registered or Published Protocol	Avoidance of Selective Outcomes Reporting	Quality Rating
Hamza, 1999	Unclear	Yes	No	Yes	Unclear	Unclear	Unclear	Poor
Pérez-Palomares, 2010	Unclear	Yes	Yes	Yes	Unclear	Unclear	Unclear	Poor

Please see Appendix C. Included Studies for full study references.

Appendix F36. Inferential Therapy RCTs

Author, Year	Randomization	Concealed Treatment Allocation	Baseline Group Similarity	Patient Blinded	Care Provider Blinded	Outcome Assessor / Data Analyst Blinded	Cointerventions Avoided or Similar
Lara-Palomo, 2012	Yes	Yes	Yes	No	No	Unclear	Unclear

Appendix F36. Inferential Therapy RCTs

Author, Year	Compliance Acceptable in all Groups	Attrition Reported	Attrition Acceptable	Timing of Outcome Assessment in all Groups Similar	Intention-to-Treat Analysis	Is There a Registered or Published Protocol	Avoidance of Selective Outcomes Reporting	Quality Rating
Lara-Palomo, 2012	Unclear	Yes	Yes	Yes	Yes	Unclear	Yes	Fair

Please see Appendix C. Included Studies for full study references.

Appendix F37. Heat-Cold SRs

Author, Year	"A priori" design provided?	Duplicate study selection and data abstraction? a. Study selection b. Data abstraction	Comprehensive literature search performed?	Non-English language studies considered for inclusion?	Conducted searches for unpublished (gray) literature?	List of included studies provided?	List of excluded studies provided with reasons?	Characteristics of the included studies provided?
French 2005	Yes	a. Yes b. Yes	Yes	Unclear	Unclear	Yes	Yes (no reasons for exclusion provided)	Yes

Appendix F37. Heat-Cold SRs

Author, Year	Scientific quality of included studies: a. Assessed? b. Documented?	Sensitivity analyses or stratified analyses conducted according to study quality?	Study conclusions supported by the evidence? (Was study quality considered in the synthesis?)	Conflict of interest stated? a) Systematic Review b) Individual Studies	Multidisciplinary systematic review team?	Quality Rating
French 2005	a. Yes b. Yes	No	Yes	a. Yes b. No	Yes	Good

Please see Appendix C. Included Studies for full study references.

Appendix F38. Superficial Heat/Cold RCTs

Author, Year	Randomization	Concealed Treatment Allocation	Baseline Group Similarity	Patient Blinded	Care Provider Blinded	Outcome Assessor / Data Analyst Blinded	Cointerventions Avoided or Similar	Compliance Acceptable in All Groups
Kettenmann 2007	Unclear	Unclear	Yes	No	Unclear	Unclear	Yes	Unclear

Appendix F38. Superficial Heat/Cold RCTs

Attrition Reported	Attrition Acceptable	Timing of Outcome Assessment in all Groups Similar	Intention-to-Treat Analysis	Is There a Registered or Published Protocol	Avoidance of Selective Outcomes Reporting	Quality
Yes	No	Yes	No	Unclear	Unclear	Fair

Please see Appendix C. Included Studies for full study references.

Appendix F40. LLLT RCTs

Author, Year	Randomization	Concealed Treatment Allocation	Baseline Group Similarity	Patient Blinded	Care Provider Blinded	Outcome Assessor / Data Analyst Blinded	Cointerventions Avoided or Similar	Compliance Acceptable in All Groups
Ay 2010	Yes	Unclear	Yes	Yes	No	Yes	Yes	Yes
Djavid 2007	Unclear	Yes	Yes	Unclear	Yes	Yes	Unclear	Yes
Jovicic 2012	Unclear	Unclear	Yes	Yes	Unclear	Unclear	Yes	Yes
Konstantinovic 2010	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

Appendix F40. LLLT RCTs

Author, Year	Attrition Reported	Attrition Acceptable	Timing of Outcome Assessment in all Groups Similar	Intention-to-Treat Analysis	Is There a Registered or Published Protocol	Avoidance of Selective Outcomes Reporting	Quality Rating
Ay 2010	Yes	Yes	Yes	Yes	Unclear	Unclear	Good
Djavid 2007	Yes	Yes	Yes	No	Unclear	Unclear	Fair
Jovicic 2012	Yes	Yes	Yes	Yes	Unclear	Unclear	Fair
Konstantinovic 2010	Yes	Yes	Yes	Yes	Unclear	Unclear	Good

Please see Appendix C. Included Studies for full study references.

Appendix F41. Lumbar Supports SRs

Author, Year	"A priori" design provided?	Duplicate study selection and data abstraction? a. Study selection b. Data abstraction	Comprehensive literature search performed?	Non-English language studies considered for inclusion?	Conducted searches for unpublished (gray) literature?	List of included studies provided?	List of excluded studies provided with reasons?	Characteristics of the included studies provided?
van Duijvenbode 2008	Yes	a. Yes b. Yes	Yes	Yes	Unclear	Yes	Yes	Yes

Appendix F41. Lumbar Supports SRs

Author, Year	Scientific quality of included studies: a. Assessed? b. Documented?	Sensitivity analyses or stratified analyses conducted according to study quality?	Study conclusions supported by the evidence? (Was study quality considered in the synthesis?)	Conflict of interest stated? a) Systematic Review b) Individual Studies	Multidisciplinary systematic review team?	Quality Rating
van Duijvenbode 2008	a. Yes b. Yes	Yes	Yes	a. Yes b. No	Yes	Good

Please see Appendix C. Included Studies for full study references.

Appendix F43. Lumbar Supports RCTs

Author, Year	Randomization	Concealed Treatment Allocation	Baseline Group Similarity	Patient Blinded	Care Provider Blinded	Outcome Assessor / Data Analyst Blinded	Cointerventions Avoided or Similar
Studies published since the APS and Cochrane reviews							
Calmels 2009	Yes	Unclear	Yes (reported in text; data not shown for some characteristics)	No	No	Unclear	Yes
Oleske 2007	Yes	Yes	Yes	No	No	Yes	Yes
Sato 2012	Yes	Unclear	Yes (reported in text; data not shown)	No	No	Unclear	Yes

Appendix F43. Lumbar Supports RCTs

Author, Year	Compliance Acceptable in all Groups	Attrition Reported	Attrition Acceptable	Timing of Outcome Assessment In All Groups Similar	Intention-to-Treat Analysis	Is There a Registered or Published Protocol	Avoidance of Selective Outcomes Reporting	Quality Rating
Studies published since the APS and Cochrane reviews								
Calmels 2009	Unclear	Yes	Yes	Yes	No	Unclear	Unclear	Fair
Oleske 2007	Unclear	Yes	Yes	Yes	Yes	Unclear	Unclear	Fair
Sato 2012	Unclear	Yes	Yes	Yes	No	Unclear	Unclear	Fair

Please see Appendix C. Included Studies for full study references.

Appendix F44. Traction RCTs

Author, year	Randomization	Concealed treatment allocation	Baseline group similarity	Patient blinded	Care provider blinded	Outcome assessor / Data analyst blinded	Cointerventions avoided or similar	Compliance acceptable in all groups
Studies published since the APS and Cochrane reviews								
Diab 2012 and Diab 2013	Yes	Yes	Yes	No	No	No	Yes	Yes
Moustafa 2013	Yes	Yes	Yes	No	Unclear	Unclear	Yes	Yes
Prasad 2013	Unclear	Unclear	Yes	No	Yes	Unclear	Yes	Unclear

Appendix F44. Traction RCTs

Author, year	Attrition reported	Attrition acceptable	Timing of outcome assessment in all groups similar	Intention-to-treat analysis	Is there a registered or published protocol	Avoidance of selective outcomes	Quality Rating
Studies published since the APS and Cochrane reviews							
Diab 2012 and Diab 2013	Yes	Yes	Yes	Unclear	Yes	Yes	Fair
Moustafa 2013	Yes	Yes	Yes	Yes	Unclear	Unclear	Fair
Prasad 2013	Yes	No	Yes	No	Unclear	Unclear	Poor

Please see Appendix C. Included Studies for full study references.

Appendix F45. Taping RCTs

Author, Year	Randomization	Concealed Treatment Allocation	Baseline Group Similarity	Patient Blinded	Care Provider Blinded	Outcome Assessor / Data Analyst Blinded	Cointerventions Avoided or Similar	Compliance Acceptable in All Groups
Castro-Sanchez, 2012	Yes	Yes	Yes	Yes	No	Yes	Unclear	Yes
Chen, 2012	Unclear	Unclear	Yes	No	No	Yes	Unclear	Unclear
Kachanathu, 2014	Unclear	Unclear	Unclear	No	No	Unclear	Unclear	Unclear
Paolini, 2011	Yes	Unclear	Yes	No	No	Unclear	Unclear	Unclear
Parreira, 2014	Yes	Yes	Yes	Yes	No	Yes	Unclear	Yes

Appendix F45. Taping RCTs

Author, Year	Attrition Reported	Attrition Acceptable	Timing of Outcome Assessment in all Groups Similar	Intention-to-Treat Analysis	Is There a Registered or Published Protocol	Avoidance of Selective Outcomes Reporting	Quality Rating
Castro-Sanchez, 2012	Yes	Yes	Yes	Yes	Unclear	Yes	Good
Chen, 2012	Yes	Yes	Yes	Yes	Unclear	Yes	Fair
Kachanathu, 2014	No	Unclear	Yes	Unclear	Unclear	Yes	Poor
Paolini, 2011	No	Unclear	Yes	Unclear	Unclear	Yes	Fair
Parreira, 2014	Yes	Yes	Yes	Yes	Yes	Yes	Good

Please see Appendix C. Included Studies for full study references.

Appendix G. Outcome Measures

Outcome measure	Measure description	Score range and direction	Topics
12-Item Short Form Health Survey (SF-12)	A multipurpose short form survey with 12 questions, all selected from the SF-36 Health Survey ; questions are combined, scored, and weighted to create two scales that provide glimpses into mental and physical functioning and overall health-related-quality of life	Scores of twelve questions and range from 0 to 100 (zero score indicates the lowest level of health and 100 indicates the highest level of health)	Antiseizure Medications; Opioids; Psychological Therapies;
Athens Insomnia Scale (AIS)	The scale assesses the severity of insomnia; evaluates sleep onset, night and early-morning waking, sleep time, sleep quality, frequency and duration of complaints, distress caused by the experience of insomnia, and interference with daily functioning.	Respondents use Likert-type scales to show how severely certain sleep difficulties have affected them during the past month. Scores range from 0 (meaning that the item in question has not been a problem) to 3 (indicating more acute sleep difficulties)	Antidepressants
Beck Depression Inventory (BDI)	The BDI is a 21-item measure of depressive symptomatology, including items assessing both cognitive and somatic complaints associated with depression. Survey is completed by patient	Scored on 0 to 3 scale Minimal: 0 Severe: 3 Each item represents a symptom or belief that is rated from 0 to 3 in terms of intensity. The BDI consists of 21 groups of statements, and after reading each group of statements, participants mark the statement in each group that best describes the way they have been feeling over the previous week.	Electrical Stimulation
BPI- Short Form (BPI-SF)	A 9 item self-administered questionnaire used to evaluate the severity of a patient's pain and the impact of this pain on the patient's daily functioning	Rating of: worst, least, average, and current pain intensity, list current treatments and their perceived effectiveness, and rate the degree that pain interferes with general activity, mood, walking ability, normal work, relations with other persons, sleep, and enjoyment of life on a 10 point scale. (Higher score indicates higher level of pain)	Antiseizure Medications
Brief Pain Inventory (BPI)	To assess the severity of pain and the impact of pain on daily functions	The BPI assesses pain at its “worst,” “least,” “average,” and “now” (current pain). In clinical trials, the items “worst” and “average” have each been used singly to represent pain severity. A composite of the four pain items (a mean severity score) is sometimes presented as supplemental information.	Antidepressants; Opioids
Center for Disease Control and Prevention health-related quality of life Questionnaire (CDC HRQOL– 4)	4 item questionnaire to measure General health and the number of recent days when a person was physically unhealthy, mentally unhealthy,	Responses to questions 2 and 3 are combined to calculate a summary index of overall unhealthy days, with a logical maximum of 30 unhealthy days. Healthy days are the positive	Yoga

	or limited in usual activities.	complementary form of unhealthy days.	
Chronic Pain Acceptance Questionnaire (CPAQ)	A 20-item inventory measuring acceptance of pain	Two subscales: activity engagement (AE) and pain willingness (PW). Participants rate items on a scale from 0 (never true) to 6 (always true). Higher scores denote greater activity engagement and pain willingness (pain willingness items are reverse scored	Psychological Therapies
Chronic Pain Self Efficacy Scale (PSEQ)	A 10-item questionnaire to assess the confidence people with ongoing pain have in performing activities while in pain.	A 7-point Likert scale (0-6) 0= not at all confident 6= completely confident A total score ranging from 0 to 60 is calculated by adding the scores for each item. Higher score reflect stronger self-efficacy beliefs	Psychological Therapies
Clinical Global Impressions of Severity Scale (CGI-S)	Provides an overall clinician-determined summary measure that takes into account all available information, including a knowledge of the patient's history, psychosocial circumstances, symptoms, behavior, and the impact of the symptoms on the patient's ability to function	Scale: 1-7 Ranging from 1 (normal) to 7 (extremely ill)	Antidepressants
Dallas Pain Questionnaire (DPQ)	Assess the amount of chronic spinal pain that affects four aspects of the patients' lives: Daily activities, work-leisure activities, anxiety-depression, and social interest/	A 16-item visual analog scale, with each item broken down into 5 to 8 small segments; each item contains its own visual analog scale. Each segment is marked with an 'x' by the subject – this indicates where their pain impact falls on that continuum. The scales range from "no pain" or 0%, to "some" pain, to "all the time" and 100% impact of pain. Each item in assigned a value, then individual rating are summed and multiplies bay a constant for a percentage of pain impact for each of the four aspects of the patients' lives.	TENS
EuroQoL (EQ-5D)	Designed for the collection of health state values using a VAS rating scale. It's only distributed in instances where researchers specifically wish to elicit valuations of health.	A vertical 20 cm visual analogue scale with the end points labelled best imaginable health state at the top and worst imaginable health state at the bottom having numeric values of 100 and 0 respectively.	Antidepressants; Antiseizure Medications; Interferential therapy; Opioids; Psychological Therapies
Fear Avoidance Beliefs Questionnaire (FABQ)	Measures patients' fear of pain and consequent avoidance of physical activity because of their fear	This questionnaire consists of 16 items, with 2 subscales, the Work Subscale and the Physical Activity Subscale; each item is scored from 0-6. Higher scores on the FABQ are indicative of greater fear and avoidance beliefs.	Psychological Therapies
Functional Rating Index (FRI)	An instrument specifically designed to quantitatively measure the subjective	A 10-item assessment with a 5 point scale ranked by the patient; 0 = no pain or full ability to	Ultrasound

Appendix G. Outcome Measures

	perception of function and pain of the spinal musculoskeletal system in a clinical environment	function; 4 = worst possible pain and/or unable to perform this function at all. The index score is achieved by simply summing up the equally weighted scores, dividing by the total number of possible points, and multiplying by one hundred percent. The range of scores is zero percent (no disability) to 100% (severe disability). {(total score/40) x 3 100%}	
Geriatric Depression Scale (GDS)	Developed as a basic screening measure for depression in older adults	normal-0-9; mild depressives-10-19; severe depressives-20-30	PENS
The Hospital Anxiety and Depression Scale (HADS)	Instrument for detecting states of depression and anxiety in the setting of an hospital medical outpatient clinic	There are 14 items; 7 regarding depression and 7 regarding anxiety. Score for each subscale (anxiety and depression) can range from 0-21 with scores categorized as follows: normal (0-7), mild (8-10), moderate (11-14), severe (15-21). Scores for the entire scale (emotional distress) range from 0-42, with higher scores indicating more distress	Antiseizure Medications
Illness Perceptions Questionnaire-Revised (IPQ-R)	An 84-item self-completed instrument developed to provide a quantitative measurement of the components of illness representations, as described by Leventhal's Common-Sense Model (CSM) of self regulation.	Divided into three sections: identity subscale (14 symptoms), causal subscale (18 causes), and a third section which contains 7 subscales, including consequences, timeline acute/chronic and cyclical, personal and treatment control/cure, illness coherence, and emotional representations. For the identity subscale, patients respond by circling 'yes' or 'no' to each question. For the causal subscale, patients respond to each of the listed causes using a 5-point Likert style scale, ranging from strongly disagree to strongly agree. The third section (7 subscales) is scored by summing responses to each item is on a 5-point Likert style scale, ranging from strongly disagree to strongly agree. All items for each of the subscales are summed to give an overall score.	Psychological Therapies
Isotechnologies B-200	A computerized isodynamic system providing information about the functional characteristics of the low back	Parameters measured included: Range of motion, isometric torque, and isodynamic velocities in all three major axes.	LLLT
Japanese Orthopedic Association (JOA)	An objective assessment scale quantitating the severity of the spondylotic myelopathy.	Results are scored on a 23 point scale. Total is based on the sum 2 sub scales: 'Subjective systems' (0-9); (ADL) Activities of daily living, (0-14). Higher point scores indicate improved symptoms.	Lumbar Supports

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Leeds Assessment of Neuropathic Symptoms and Signs (LANSS)	Tool used in identifying patients in whom neuropathic mechanisms dominate their pain experience.	If score < 12, neuropathic mechanisms are unlikely to be contributing to the patient's pain. If score ≥ 12, neuropathic mechanisms are likely to be contributing to the patient's pain	Antiseizure Medications
Low Back Pain Outcome Instrument (LBPOI)	A comprehensive back pain Questionnaire designed to be applicable to a varied population of patients with back pain	6 summative subscales based on 34 items: back pain, neurogenic symptoms, job exertion, job stress/satisfaction, expectations for treatment, and additionally the Short Form 36 (SF36) mental health subscale Discrete, linear values are calculated for each Subscale. The numeric range of response is 1 through 6.	Electrical Stimulation
McGill Pain Questionnaire Pain Rating Index (MPQ)	consists primarily of 3 major classes of word descriptors--sensory, affective and evaluative--that are used by patients to specify subjective pain experience	(0 to 78) minimum pain score: 0 (would not be seen in a person with true pain) maximum pain score: 78 The higher the pain score the greater the pain	Interferential therapy; PENS; TENS
McGill Pain Questionnaire Pain Rating Index- Short-Form (SF-MPQ)	A self-report measure of pain quality consisting of 15 descriptors of pain, representing both the sensory (e.g., 'throbbing', 'aching') and affective (e.g., 'sickening', 'fearful') components of pain quality. Participants are asked to indicate the extent to which each descriptor describes the severity of their pain experience.	Responses are made on a four-point Likert scale, ranging from 0 (none) to 3 (severe). Three subscale scores are calculated: sensory, affective and total pain responses	Antiseizure Medications; Psychological Therapies
Medical Outcome Study Sleep Scale (MOS Sleep Scale)	Measures six dimensions of sleep, including initiation, maintenance, quantity, adequacy, somnolence, and respiratory impairments	Ten of the scale's 12 items are scored using a six-point response scale, one item uses a five-point Likert scale, and sleep quantity is an open-ended question recording the actual number of hours slept. Sleep quantity are recalibrated on a 0–100 scale that represents the percentage of a particular sleep domain; sleep quantity is recorded as 0–24 h. Higher scores for the domains of sleep disturbance, somnolence and the sleep indices indicate worse sleep problems, whereas lower scores for sleep quantity and sleep adequacy indicate worse sleep problems	Antiseizure Medications
Multidimensional Pain Inventory (Pain Severity Scale)	A self-report instrument that measures the impact of pain on an individual's life. Pain Severity Scale, a sub-scale of the Multidimensional Pain Inventory focuses on the	Rated on a 7-point scale (0-6). Scale scores are computed by summing over all items and then the mean is composed based on the number of scale items.	PENS

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	average pain the subject has had in the past week and the corresponding Amount of suffering experienced.		
Oswestry disability index (ODI)	A self-administered outcome-measure questionnaire for low back pain in a hospital setting; divided into ten sections designed to assess limitations of various activities of daily living	For each section of six statements the total score is 5; if the first statement is marked the score = 0; if the last statement is marked it = 5. Intervening statements are scored according to rank. If more than one box is marked in each section, take the highest score. If all 10 sections are completed the score is calculated as follows: total scored/ 50 (total possible score) x 100= %	Antiseizure Medications; Electrical Stimulation; Interferential therapy; Opioids; PENS; Taping; Traction; Ultrasound
Pain Disability Index (PDI)	A seven-item self-report measure that assesses disability in seven areas: family, occupation, sexual relations, social activities, recreation, self-care and life support. Participants are asked to indicate their disability in each of the seven areas.	Each of the seven subscales is graded from zero to 10; zero (no disability) to 10 (total disability). A total disability score is determined by summing the numerical ratings of the seven disability scales (range zero to 70).	Acetaminophen; Electrical Stimulation
Pain Self Efficacy Scale (PSEQ)	A 10-item questionnaire to assess the confidence people with ongoing pain have in performing activities while in pain.	A 7-point Likert scale (0-6) 0= not at all confident 6= completely confident A total score ranging from 0 to 60 is calculated by adding the scores for each item. Higher score reflect stronger self-efficacy beliefs	Psychological Therapies
Patient Specific Functional Scale (PSFS)	Patients rate their ability to complete an activity on a 11-point scale at a level experienced prior to injury or change in functional status	mean, 0-10 (0" represents “unable to perform” "10" represents “able to perform at prior level”)	Acetaminophen
Patients' Global Impression (PGIC)	A self-reported measure which reflects a patient's belief about the efficacy of treatment	A 7 point scale depicting a patient's rating of overall improvement. (Patients rate their change as “very much improved,” “much improved,” “minimally improved,” “no change,” “minimally worse,” “much worse,” or “very much worse.”)	Antidepressants
Pittsburgh Sleep Quality Index (PSQI)	An instrument used to measure the quality and patterns of sleep in the older adults.	Based on a 0 to 3 scale, whereby 3 reflects the negative extreme on the Likert Scale. A global sum of “5”or greater indicates a “poor” sleeper	PENS
Profile of Mood States (POMS)	To assess affective mood state fluctuation	Measures six identifiable mood or affective states: 1) Tension-Anxiety 2) Vigor-Activity 3) Depression-Dejection 4) Fatigue-Inertia 5) Anger-Hostility 6) Confusion-Bewilderment; Requires respondents to indicate how well each item describes their mood over the past week using a five-point scale (0-4) ranging from	Antidepressants

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		"not at all" to "extremely."	
Quebec Back Pain disability scale (QBPDS)	A condition-specific questionnaire developed to measure the level of functional disability for patients with low back pain	There are 6 answer categories, measured by using a Likert scale from 0-5 (0 = no effort, 5 = not able to)	Opioids; Psychological Therapies
Roland Morris Back Pain disability questionnaire (RMDQ)	A self-administered disability questionnaire designed for back pain.	A 24 item questionnaire, with and individual's score ranging from 0 (no disability) to 24 (maximum disability).	Acetaminophen; Antidepressants; Antiseizure Medications; Benzodiazepine; Corticosteroids; Interferential therapy; LLLT; Opioids; PENS; Psychological Therapies; Taping; TENS; Traction; Ultrasound;
Schober test	Assesses the amount of lumbar flexion.	A mark is made at the level of the posterior iliac spine on the vertebral column, i.e. approximately at the level of L5. The examiner then places one finger 5cm below this mark and another finger at about 10cm above this mark. The patient is then instructed to touch his toes. If the increase in distance between the two fingers on the patients spine is less than 5cm then this is indicative of a limitation of lumbar flexion.	LLLT
SF12 Mental score (MCS-12)	The SF-12 is a multipurpose short form survey with 12 questions, all selected from the SF-36 Health Survey The questions are combined, scored, and weighted to create two scales that provide glimpses into mental functioning and overall health-related-quality of life	mean, 0-100 (zero score indicates the lowest level of health measured by the scales and 100 indicates the highest level of health)	Acetaminophen
SF12 Physical score (PCS-12)	The SF-12 is a multipurpose short form survey with 12 questions, all selected from the SF-36 Health Survey The questions are combined, scored, and weighted to create two scales that provide glimpses into physical functioning and overall health-related-quality of life	mean, 0-100 (zero score indicates the lowest level of health measured by the scales and 100 indicates the highest level of health)	Acetaminophen
Short Form-36 (SF-36)	36 item questionnaire which measures Quality of Life (QoL) across eight domains, which are both physically and emotionally based	0–100 (higher score indicates worse disability)	Antidepressants; Electrical Stimulation; Antidepressants; Electrical Stimulation;

Appendix G. Outcome Measures

			Interferential therapy; Opioids; PENS; Psychological Therapies; TENS; Traction; Ultrasound; Yoga
Short Opioid Withdrawal Scale (SOWS)	A 10 item scale as a measure of the opiate withdrawal response.	Four point scale: (0) none to (3) severe.	Opioids
State-trait Anxiety Inventory (STAI)	Measure of trait and state anxiety It can be used to diagnose anxiety and to distinguish it from depressive syndromes.	20 items for assessing trait anxiety and 20 for state anxiety 4-point scale. Higher score indicates greater anxiety.	Yoga
Swiss Spinal Stenosis Questionnaire (SSS)	A disease-specific self-report outcome instrument designed to complement generic measures of lumbar spine disability and health status in patients with lumbar spinal stenosis.	Symptom severity scale: the range of the scales: 1 to 5 (higher score indicates higher severity) Physical function scale: the range of the scale is 1 to 4 (higher score indicates lower function) Patient's satisfaction with treatment scale: the range of the scale is 1 to 4 (higher score indicates greater dissatisfaction)	Antiseizure Medications
Symptom Checklist-90	Helps evaluate a broad range of psychological problems and symptoms of psychopathology. The instrument is also useful in measuring patient progress or treatment outcomes	The 90 items in the questionnaire are scored on a five-point Likert scale, indicating the rate of occurrence of the symptom during the time reference. It is intended to measure symptom intensity on nine different subscales	Opioids
Visual Analogue Scale (VAS)	A unidimensional measure of pain intensity. It's a continuous scale comprised of a horizontal (HVAS) or vertical (VVAS) line, usually 10 centimeters (100 mm) in length, anchored by 2 verbal descriptors, one for each symptom extreme.	For pain intensity, the scale is most commonly anchored by "no pain" (score of 0) and "pain as bad as it could be" or "worst imaginable pain" (score of 100 [100-mm scale])	Antidepressants
Von Korff pain scale	A system for grading chronic pain and chronic disability resulting from different causes	scale 0–100%; lower scores indicate less severe pain or disability	Psychological Therapies

Appendix H. Strength of Evidence

Key Question Outcome	Study Design Number of Studies	Study Limitations	Consistency	Directness	Precision	Reporting Bias	Strength of Evidence Grade
1. What are the comparative benefits and harms of different pharmacological therapies for acute or chronic nonradicular low back pain, radicular low back pain, or spinal stenosis? (Including NSAIDs, acetaminophen, opioids, muscle relaxants, antiseizure medications, antidepressants, corticosteroids, and topicals/patch-delivered medications)							
Acetaminophen							
Acetaminophen vs. Placebo, acute LBP : Pain and function	1 RCT	Low	Unable to determine	Direct	Precise	Undetected	Moderate
Acetaminophen vs. NSAID, acute LBP: Pain and global improvement	3 RCTs	High	Consistent	Direct	Precise	Undetected	Low
Acetaminophen vs. Placebo, chronic LBP	No studies	-	-	-	-	-	Insufficient
Acetaminophen vs. NSAID, chronic LBP	1 RCT	High	Unable to determine	Direct	Imprecise	Undetected	Insufficient
Acetaminophen vs. other interventions, acute LBP	4 RCTs	High	Consistent	Direct	Imprecise	Undetected	Insufficient
Acetaminophen vs. placebo: Adverse events (serious adverse events)	1 RCT	Low	Consistent	Direct	Imprecise	Undetected	Moderate
Acetaminophen vs. NSAIDs : Adverse events	3 RCTs in systematic revie	Moderate	Consistent	Direct	Precise	Undetected	Moderate
Acetaminophen vs Placebo, NSAID or Other intervention, radicular LBP	No studies	-	-	-	-	-	Insufficient
NSAIDs							
NSAIDs vs. Placebo, acute LBP : Pain, function	4 RCTs in systematic review and 1 RCT for pain; 1 RCT for function	Moderate	Consistent for pain Unable to determine for function	Direct	Precise for pain Imprecise for function	Undetected	Moderate for pain, low for function
NSAIDs vs. Placebo, chronic LBP : Pain, function	4 RCTs in systematic review for pain 2 RCTs for function	Moderate	Consistent	Direct	Precise for pain Imprecise for function	Undetected	Moderate for pain, low for function
NSAIDs vs. Placebo, radicular LBP : Pain	2 RCTs in systemtic review	Moderate	Inconsistent	Direct	Imprecise	Undetected	Low
NSAID plus another intervention vs. Other intervention alone	2 RCTs	High	Inconsistent	Direct	Imprecise	Undetected	Insufficient
NSAIDs vs. Interventions other than acetaminophen and opioids	2 RCTs	High	Inconsistent	Direct	Imprecise	Undetected	Insufficient
NSAID vs. NSAID, acute or chronic LBP : Pain	27 RCTs	Moderate	Consistent	Direct	Precise	Undetected	Moderate

Appendix H. Strength of Evidence

Key Question Outcome	Study Design Number of Studies	Study Limitations	Consistency	Directness	Precision	Reporting Bias	Strength of Evidence Grade
NSAIDs vs. Placebo : Adverse events	10 RCTs	Moderate	C onsistent	Direct	Precise	Undetected	Moderate
COX-2-selective NSAIDs vs. nonselective NSAIDs : Adverse events	4 RCTs	Moderate	Consistent	Direct	Precise	Undetected	Moderate
Opioids							
Opioids vs. Placebo, chronic LBP : Pain and function	6 RCTs in systematic review and 3 RCTs	Moderate	Consistent	Direct	Precise	Undetected	Moderate
Tramadol vs. Placebo, chronic LBP : Pain and function	5 RCTs in systematic review and 2 RCTs	Moderate	Consistent	Direct	Precise	Undetected	Moderate
Buprenorphine patch vs. Placebo, subacute or chronic LBP : Pain and function	2 RCTs in systematic review	Moderate	Consistent for pain Inconsistent for function	Direct	Imprecise	Undetected	Low for pain Insufficient for function
Opioids vs. NSAIDs, chronic LBP : Pain relief, function	3 RCTs for pain 1RCT for function	Moderate	Inconsistent for pain Unable to determine for function	Direct	Imprecise	Undetected	Insufficient
Opioids vs. Acetaminophen, acute LBP : Days to return to work, pain	1 RCT for return to work No studies for pain	Moderate	Unable to determine	Direct	Imprecise	Undetected	Insufficient
Long acting opioids vs. Long acting opioids : Pain, function	4 RCTs	Moderate	Consistent	Direct	Precise	Undetected	Moderate
Long acting opioids vs. Short acting opioids : Pain	6 RCTs	Moderate	Inconsistent	Direct	Precise	Undetected	Low
Opioids vs. Placebo: Adverse events	16 RC Ts in systematic review	Moderate	Consistent	Direct	Precise	Undetected	Moderate
Skeletal Muscle Relaxants (SMR)							
SMRs vs Placebo, acute LBP : Pain	4 RCTs in a systematic review and 1 RCT	Moderate	Consistent	Direct	Precise	Undetected	Moderate
SMR plus NSAID vs. NSAID alone, acute LBP : Pain	2 RCTs in systematic review and 1 RCT	Moderate	Consistent	Direct	Imprecise	Undetected	Low
SMR vs. Placebo, chronic LBP : Pain	3 RCTs	Moderate	Inconsistent	Direct	Imprecise	Undetected	Insufficient
SMR vs. SMR, acute or chronic LBP : Pain	3 RCTs in systematic review	Moderate	Consistent	Direct	Imprecise	Undetected	Low
SMR vs. Placebo, acute LBP : Adverse events	8 RCTs in systematic review and 1 RCT	Moderate	Consistent	Direct	Precise	Undetected	Moderate
Benzodiazepines							

Appendix H. Strength of Evidence

Key Question Outcome	Study Design Number of Studies	Study Limitations	Consistency	Directness	Precision	Reporting Bias	Strength of Evidence Grade
Benzodiazepines vs. Placebo, acute LBP : Pain, function	2 RCTs	Moderate	Inconsistent	Direct	Imprecise	Undetected	Insufficient
Tetrazepam vs. Placebo, chronic LBP:Pain, overall improvement	2 RCTs in systematic review	Moderate	Consistent	Direct	Imprecise	Undetected	Low
Diazepam vs. Placebo, acute or subacute radicular pain : Pain, function	1 RCT	Low	Unable to determine	Direct	Precise	Undetected	Low
Benzodiazepines vs. Skeletal muscle relaxants, chronic LBP: Pain, function	2 RCTs	Low	Inconsistent	Direct	Imprecise	Undetected	Insufficient
Diazepam vs. Cyclobenzaprine, chronic LBP : Muscle spasms	1 RCT	Moderate	Unable to determine	Direct	Imprecise	Undetected	Low
Benzodiazepines vs. Placebo: Adverse events	8 RCTs in systematic review and 1 RCT	Moderate	Consistent	Direct	Imprecise	Undetected	Low
Antidepressants							
Tricyclic antidepressants or SSRI vs. Placebo, chronic LBP : Pain, function	4 RCTs of tricyclics and 3 RCTs of SSRIs in systematic review for pain; 2 RCTs evaluated function	Moderate	Consistent	Direct	Imprecise	Undetected	Moderate for pain, low for function
Duloxetine vs. Placebo, chronic LBP : Pain, Function	3 RCTs	Low	Consistent	Direct	Precise	Undetected	Moderate
Duloxetine vs. Tricyclic antidepressants	No studies	-	-	-	-	-	Insufficient
Antidepressants vs. Placebo : Adverse events, Serious adverse events	9 RCTs in systematic review and 3 RCTs	Moderate	Consistent	Direct	Precise	Undetected	Moderate
Antiseizure medications							
Antiseizure medications, acute non-radicular LBP	No studies	-	-	-	-	-	Insufficient
Gabapentin vs. Placebo, chronic non-radicular LBP	1 RCT (abstract only, excluded)	-	-	-	-	Suspected	Insufficient
Gabapentin vs. Placebo, chronic radicular LBP: Pain and function	3 RCTs	High	Inconsistent	Direct	Imprecise	Undetected	Insufficient
Topiramate vs. Placebo, chronic radicular or mixed radicular and non-radicular LBP: Pain	2 RCTs	Moderate	Inconsistent	Direct	Imprecise	Undetected	Insufficient
Pregabalin vs. Placebo, chronic radicular LBP : pain, function	2 RCTs	Moderate	Inconsistent	Direct	Imprecise	Undetected	Insufficient
Pregabalin plus transdermal buprenorphine vs. transdermal buprenorphine, chronic non-radicular LBP : Pain	1 RCT	Moderate	Unable to determine	Direct	Imprecise	Undetected	Insufficient
Pregabalin plus another anaglesic vs. the other analgesica alone: Pain	2 RCTs	Moderate	Inconsistent	Direct	Imprecise	Undetected	Insufficient

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Key Question Outcome	Study Design Number of Studies	Study Limitations	Consistency	Directness	Precision	Reporting Bias	Strength of Evidence Grade
Gabapentin vs. Placebo : Adverse events	2 RCTs	Moderate	Consistent	Direct	Imprecise	Undetected	Low
Topiramate vs. Placebo : Withdrawal due to adverse events, sedation, diarrhea	2 RCTs	Moderate	Inconsistent	Direct	Imprecise	Undetected	Insufficient
Pregabalin vs. Placebo : Withdrawal due to adverse events, somnolence, dizziness	2 RCTs	Moderate	Inconsistent	Direct	Imprecise	Undetected	Insufficient
Corticosteroids							
Systemic corticosteroids vs. Placebo, acute non-radicular LBP : Pain, function	2 RCTs	Moderate	Consistent	Direct	Imprecise	Undetected	Low
Systematic corticosteroids vs. Placebo, radicular LBP : Pain, function	5 RCTs	Moderate	Consistent	Direct	Precise	Undetected	Moderate
Systemic corticosteroids : Adverse events	12 RCTs	Moderate	Consistent	Direct	Imprecise	Undetected	Low
2. What are the comparative benefits and harms of different nonpharmacological, noninvasive therapies for acute or chronic nonradicular low back pain, radicular low back pain, or spinal stenosis?							
Exercise							
Exercise vs. Usual care, acute to subacute LBP : Pain, function	8 RCTs in systematic review and 3 RCTs	Moderate	Consistent	Direct	Imprecise	Undetected	Low
Exercise vs. Usual care, chronic LBP: Pain, Function	19 RCTs in systematic review 3 RCTs in another systematic review, and 20 RCTs	Moderate	Consistent	Direct	Precise	Undetected	Moderate
Exercise vs. Usual care, non- acute LBP: Work disability	8 RCTs in systematic review	Moderate	Consistent	Direct	Precise	Undetected`	Moderate
Exercise vs. Usual care, radicular LBP: Pain, function	3 RCTs	Moderate	Consistent	Direct	Imprecise	Undetected	Low
Exercise vs. Exercise, acute or chronic LBP	>20 RCTs	Moderate	Consistent	Direct	Precise	Suspected	Moderate
Exercise : Adverse events							Low
Motor Control Exercise [MCE]							
MCE vs. General exercise, chronic LBP : Pain, function	6 RCTs in systematic review and 2 RCTs	Moderate	Consistent	Direct	Imprecise	Undetected	Low
MCE vs. Minimal intervention, chronic LBP : Pain, function	2 RCTs for pain and 3 RCTs for function in systematic review	Modeate	Consistent	Direct	Imprecise	Undetected	Low

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Key Question Outcome	Study Design Number of Studies	Study Limitations	Consistency	Directness	Precision	Reporting Bias	Strength of Evidence Grade
MCE vs. Multimodal PT, chronic LBP : Pain, function	4 RCTs for pain and 2 RCTs for function in systematic review	Moderate	Consistent	Direct	Imprecise	Undetected	Low
MCE plus exercise vs. Exercise alone	2 RCTs	Moderate	Consistent	Direct	Imprecise	Undetected	Low
MCE : Adverse events	6 RCTs	Moderate	Consistent	Direct	Precise	Suspected	Low
Pilates							
Pilates vs. usual care plus physical activity, chronic LBP: Pain, function	7 RCTs in systematic review	Moderate	Inconsistent	Direct	Precise	Undetected	Low
Pilates vs. other exercise, chronic LBP: Pain, function	3 RCTs in systematic review	Moderate	Consistent	Direct	Imprecise	Undetected	Low
Tai Chi							
Tai Chi vs. waitlist or no Tai Chi, chronic LBP : Pain, function	2 RCTs for pain, 1 RCT for function	Moderate	Consistent for pain Unable to determine for function	Direct	Imprecise	Undetected	Low
Tai Chi vs. other exercise, chronic LBP : Pain	1 RCT	Moderate	Unable to determine	Direct	Imprecise	Undetected	Low
Tai Chi : Adverse events	2 RCTs	Moderate	Unable to determine	Direct	Imprecise	Undetected	Low
Yoga							
Yoga vs. Usual care, chronic LBP :Pain, Function	1 RCT	Moderate	Unable to determine	Direct	Imprecise	Undetected	Low
Yoga vs. Exercise, chronic LBP : Pain, Function	5 RCTs in sytematic review	Moderate	Consistent	Direct	Imprecise	Undetected	Low
Yoga vs. Education, chronic LBP : Pain, function	5 RCTs	Moderate	Consistent	Direct	Precise	Undetected	Moderate
Yoga : Adverse events	5 RC Ts	Moderate	Consistent	Direct	Imprecise	Suspected	Low
Psychological Therapies							
Progressive relaxation vs. wait list control, chronic LBP : Pain, Function	3 RCTs in systematic review	Moderate	Inconsistent	Direct	Precise	Undetected	Low
EMG biofeedback, chronic LBP : Pain, Function	3 RCTs in systematic review	Moderate	Consistent	Direct	Imprecise	Undetected	Low
Operant therapy, chronic LBP : Pain, Function	3 RCTs for pain, 2 RCTs for function in systematic review	Moderate	Consistent	Direct	Imprecise	Undetected	Low
Cognitive therapy vs. Wait list control, chronic LBP	2 RCTs in systematic review	Moderate	Inconsistent	Direct	Imprecise	Undetected	Insufficient
Cognitive-behavioral and other combined therapy vs. Wait list control, chronic LBP : Pain, Function	5 RCTs for pain, 4 RCTs for function in systematic review	Moderate	Consistent	Direct	Imprecise	Undetected	Low

Appendix H. Strength of Evidence

Key Question Outcome	Study Design Number of Studies	Study Limitations	Consistency	Directness	Precision	Reporting Bias	Strength of Evidence Grade
Psychological therapies vs. exercise or physical therapy, chronic LBP : Pain	8 RCTs	Moderate	Inconsistent	Direct	Precise	Undetected	Low
Psychological therapies vs. Psychological therapies : Pain, Function	10 RCTs	Modeate	Inconsistent	Direct	Precise	Undetected	Moderate
Psychological therapies : Adverse events	28 RCTs in systematic review	High	Consisent	Direct	Imprecise	Suspected	Low
Multidisciplinary rehabilitation							
Multidisciplinary rehabilitation vs. Usual care, chronic LBP : Pain, function, return to work	9 RCTs in systematic review	Moderate	Inconsistent	Direct	Precise	Undetected	Moderate
Multidisciplinary rehabilitation vs. No multidisciplinary rehabilitation, chronic LBP : Pain, function	3 RCTs in systematic review	Moderate	Consistent	Direct	Imprecise	Undetected	Low
Multidisciplinary rehabilitation vs. Physical therapy, chronic LBP : Pain, function	13 RCTs in systematic review	Moderate	Inconsistent	Direct	Precise	Undetected	Moderate
Multidisciplinary rehabilitation, acute LBP, radicular LBP	No studies						Insufficient
Multidisciplinary rehabilitation : Adverse events	2 RCTs	High	Consistent	Direct	Imprecise	Suspected	Insufficient
Acupuncture							
Acupuncture vs. Sham acupuncture, subacute LBP : Pain	3 RCTs in systematic review and 2 RCTs	Moderate	Consistent	Direct	Imprecise	Undetected	Low
Acupuncture vs. Sham acupuncture, chronic LBP : Pain, function	7 RCTs in systematic review and 1 RCT	Moderate	Inconsistent	Direct	Precise	Undetected	Low
Acupuncture vs. No acupuncture, chronic low back pain	5 RCTs in systematic review	Moderate	Inconsistent	Direct	Precise	Undetected	Moderate
Acupuncture vs. NSAIDs, acute LBP : Overall improvement	5 RCTs in systematic review	Moderate	Consistent	Direc t	Imprecise	Undetected	Low
Acupuncture vs. Medications, chronic LBP : Pain, Function	3 RCTs in systematic review	High	Consistent	Direct	Precise	Undetected	Low
Acupuncture : Adverse events	3 RCTs	Moderate	Consistent	Direct	Imprecise	Undetected	Low
Massage							
Massage vs. Sham massage, acute LBP: Pain, function	2 RCTs in systematic review	Moderate	Consistent	Direct	Imprecise	Undetected	Low
Massage vs. Usual care, chronic LBP: Pain, function	2 RCTs	Moderate	Inconsistent	Direct	Precise	Undetected	Low
Massage vs. Other interventions, subacute to chronic LBP: Pain, function	9 RCTs for pain and 4 RCTs for function in systematic review	Moderate	Consistent	Direct	Precise	Undetected	Moderate

Appendix H. Strength of Evidence

Key Question Outcome	Study Design Number of Studies	Study Limitations	Consistency	Directness	Precision	Reporting Bias	Strength of Evidence Grade
Massage plus another active intervention vs. the Other intervention alone, subacute to chronic low back pain: Pain, function	5 RCTs in systematic review	Moderate	Consistent	Direct	Imprecise	Undetected	Low
Massage vs. massage: Pain, function	6 RCTs	High	Inconsistent	Direct	Imprecise	Undetected	Insufficient
Massage: Adverse events	12 RCTs	High	Consistent	Direct	Prec ise	Suspected	Low
Spinal manipulation							
Spinal manipulation, acute LBP : Pain, function	1 RCT for pain and 2 RCTs for function	High	Unable to determine for pain Consistent for function	Direct	Imprecise	Undetected	Low for function Insufficient for pain
Spinal manipulation vs. Sham manipulation, chronic LBP : Pain, function	3 RCTs in systematic review and 1 RCT	Moderate	Inconsistent	Direct	Precise	Undetected	Low for pain Insufficient for function
Spinal manipulation vs. Intert treatment, acute LBP : Pain, Function	3 RCTs in systematic review	Moderate	Consistent	Direct	Imprecise	Undetected	Low
Spinal manipulation vs. Inert treatment, chronic LBP	4 RCTs in systematic review and 3 RCTs	Modeate	Inconsistent	Direct	Precise	Undetected	Low
Spinal manipulation vs. Other active interventions, acute LBP : Pain, function	3 RCTS in systematic review	Moderate	Consistent	Direct	Imprecise	Undetected	Moderate
Spinal manipulation vs. Other interventions, chronic LBP : Pain, function	6 RCTs in systematic review and 2 RCTs	Moderate	Consistent	Direct	Precise	Undetected	Moderate
Spinal manipulation plus exercise or advice vs. exercise or advice alone, acute LBP : Function	4 RCTs in systematic review	Moderate	Consistent	Direct	Imprecise	Undetected	Low
Spinal manipulation plus another active treatment, chronic LBP : Pain, function	3 RCTS in systematic review	Moderate	Consistent	Direct	Imprecise	Undetected	Low
Spinal manipulation : Adverse events	55 RCTs	Moderate	Consistent	Direct	Precise	Suspected	Low
Ultrasound							
Ultrasound vs. Sham ultrasound, chronic LBP : Pain, function	5 RCTs	Moderate	Consistent for pain Inconsistent for function	Direct	Imprecise	Undetected	Low for pain Insufficient for function
Ultrasound vs. No ultrasound, chronic LBP : Pain, function	2 RCTs	Moderate	Consistent	Direct	Imprecise	Undetected	Low
Ultrasound plus exercise vs. Exercise, chronic LBP : Pain, Function	2 RCTs	High	Consistent	Direct	Imprecise	Undetected	Insufficient
Ultrasound vs. Other interventions	3 RCTs	High	Inconsistent	Direct	Imprecise	Undetected	Insufficient
Ultrasound vs. Other interventions, radiculopathy	1 RCT	High	Unable to determine	Direct	Imprecise	Undetected	Insufficient

Appendix H. Strength of Evidence

Key Question Outcome	Study Design Number of Studies	Study Limitations	Consistency	Directness	Precision	Reporting Bias	Strength of Evidence Grade
Ultrasound, acute non-radicular LBP	No studies						Insufficient
Ultrasound vs. Sham ultrasound : Adverse events	1 RCT	Low	Unable to determine	Direct	Imprecise	Suspected	Low
Transcutaneous electrical nerve stimulation [TENS]							
TENS vs. Sham TENS, acute or subacute LBP: Pain, function	2 RCTs	High	Unable to determine	Direct	Imprecise	Undetected	Insufficient
TENS vs. Sham TENS, chronic LBP : Pain, function	4 RCTs for pain and 2 RCTs for function in systematic review	Moderate	Consistent	Direct	Iimprecise	Undetected	Low
TENS vs. Acupuncture, chronic LBP : Pain	4 RCTs for pain and 2 RCTs for function in systematic review	Moderate	Consistent	Direct	Imprecise	Undetected	Low
TENS : Adverse events	8 RCTs in systematic review	Moderate	Consistent	Direct	Imprecise	Suspected	Low
Electrical muscle stimulation [EMS]							
EMS plus exercise vs. Exercise, EMS vs. Other interventions, acute or chronic LBP: Pain, function	5 RCTs	Moderate	Inconsistent	Direct	Imprecise	Undetected	Insufficient
EMS: Adverse events	1 RCT	Moderate	Unable to determine	Direct	Imprecise	Suspected	Insufficient
Percutaneous Electrical Nerve Stimulation [PENS]							
PENS vs. Sham PENS, PENS plus exercise vs. exercise, PENS vs. other interventions, chronic LBP (with or without radiculopathy)	6 RCTs	High	Inconsistent	Direct	Imprecise	Undetected	Insufficient
PENS : Adverse events	No studies					Suspected	Insufficient
Interferential therapy [IFT]							
IFT vs. other interventions, IFT plus another intervention vs. the other intervention,subacute to chronic LBP: Pain, function	4 RCTs	High	Inconsistent	Direct	Imprecise	Undetected	Insufficient
IFT : Adverse events	No studies					Suspected	Insufficient
Superficial Heat or Cold							
Heat wrap vs. Placebo, acute or subacute LBP : Pain, function	2 RCTs in systematic review and 2 RCTs	Moderate	Consistent	Direct	Precise	Undetected	Moderate
Heat plus exercise vs. exercise alone, acute LBP : Pain, function	1 RCT	Low	Unable to determine	Direct	Imprecise	Undetected	Low
Heat vs. Simple analgesics, acute or subacute LBP : Pain, function	1 RCT in systematic review	Low	Unable to determine	Direct	Imprecise	Undetected	Low

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Key Question Outcome	Study Design Number of Studies	Study Limitations	Consistency	Directness	Precision	Reporting Bias	Strength of Evidence Grade
Heat vs. Exercise, acute LBP : Pain, Function	1 RCT in systematic review	Low	Unable to determine	Direct	Imprecise	Undetected	Low
Superficial Cold vs. Placebo	No studies						Insufficient
Heat vs. Cold	2 RCTs	High	Consistent	Direct	Imprecise	Undetected	Insufficient
Heat vs. No heat or placebo : Adverse events, flushing	2 RCTs	Low	Consistent	Direct	Imprecise	Suspected	Low
Low Level Laser Therapy [LLLT]							
LLLT vs. Sham laser, acute LBP	1 RCT	High	Unable to determine	Direct	Imprecise	Undetected	Insufficient
LLLT vs. Sham laser, chronic LBP : Pain, Function	3 RCTs for pain, 1 RCT for function	Moderate	Consistent	Direct	Imprecise	Undetected	Low
LLLT plus NSAID vs. Sham plus NSAID, acute or subacute LBP : Pain, function	1 RCT	Low	Unable to determine	Direct	Imprecise	Undetected	Low
LLLT plus another intervention vs. the other intervention alons, chronic LBP: Pain, function	3 RCTs	Moderate	Inconsistent	Direct	Imprecise	Undetected	Insufficient
LLLT vs. anotehr intervention: Pain, function	2 RCTs	High	Unable to determine	Direct	Imprecise	Undetected	Insufficient
LLLT differing wavelengths or doses	1 RCT	Moderate	Unable to determine	Direct	Imprecise	Undetected	Insufficient
LLLT : Adverse events	10 RCTs	High	Consistent	Direct	Imprecise	Suspected	Insufficient
Short-wave Diathermy							
Short-wave diathermy vs. Sham diathermy, mixed duration LBP : Effectiveness, Adverse events	4 RCTs	High	Inconsistent	Direct	Imprecise	Undetected	Insufficient
Short-wave diathermh: Adverse events	No studies					Suspected	Insufficient
Lumbar Supports							
Lumbar supports vs. no lumbar supports or an inactive treatment, acute or subacute LBP: Pain, function	4 RCTs in systematic review and 1 RCT	Moderate	Inconsistent	Direct	Imprecise	Undetected	Insufficient
Lumbar supports vs. no lumbar supports, chronic LBP	2 RCTs	Moderate	Inconsistent	Direct	Imprecise	Undetected	Insufficient
Lumbar support plus education vs. education, acute or subacute LBP : Pain, function	1 RCT	Moderate	Unable to determine	Direct	Imprecise	Undetected	Low
Lumbar support plus exercise vs. exercise alone, chronic LBP : Pain, function	1 RCT	Moderate	Unable to determine	Direct	Imprecise	Undetected	Low
Lumbar support vs. other active treaatments : Pain, Function	3 RCTs	Moderate	Inconsistent	Direct	Imprecise	Undetected	Low
Lumbar supports vs. Lumbar supports: Pain, function	2 RCTs	Moderate	Inconsistent	Direct	Imprecise	Undetected	Insufficient
Lumbar supports : Adverse events	8 RCTs in systematic review and 3 RCTs	Moderate	Consistent	Direct	Imprecise	Suspected	Low

Appendix H. Strength of Evidence

Key Question Outcome	Study Design Number of Studies	Study Limitations	Consistency	Directness	Precision	Reporting Bias	Strength of Evidence Grade
Traction							
Traction vs. placebo, sham or no treatment, LBP with or without radicular symptoms : Pain, function	13 RCTs in systematic review and 2 RCTs	Moderate	Inconsistent	Direct	Imprecise	Undetected	Insufficient
Traction vs. physiotherapy, LBP with or without radicular symptoms: Pain, function	5 RCTs in systematic review	Moderate	Consistent	Direct	Imprecise	Undetected	Low
Traction vs. other interventions, LBP with or without radicular symptoms : Pain, function	15 RCTs in systematic review	Moderate	Consistent	Direct	Imprecise	Undetected	Low
Traction vs. Traction: Pain, function	5 RCTs in systematic review	Moderate	Consistent	Direct	Imprecise	Undetected	Low
Traction : Adverse events	11 RCTs in systematic reviews	Moderate	Consistent	Direct	Imprecise	Undetected	Low
Taping							
Kinesio Taping vs. Sham taping, chronic LBP : Pain, function	2 RCTs	Low	Inconsistent for pain Consistent for function	Direct	Imprecise	Undetected	Insufficient for pain Low for function
Functional Fascial Taping plus exercise vs. Sham taping plus exercise, chronic LBP: Pain, function	1 RCT	Moderate	Unable to determine	Direct	Imprecise	Undetected	Insufficient
Kinesio Taping vs. exercise therapy, chronic LBP : Pain, Function	2 RCTs	Moderate	Inconsistent	Direct	Imprecise	Undetected	Low
Taping : Adverse events							Insufficient